Llywodraeth Cymru
Welsh Government

HUMAN TRANSPLANTATION (WALES) BILL

Explanatory Memorandum

incorporating the Regulatory Impact Assessment and Explanatory Notes

25 June 2013

HUMAN TRANSPLANTATION (WALES) BILL

Explanatory Memorandum to the Human Transplantation (Wales) Bill

This Explanatory Memorandum has been prepared by the Department for Health and Social Services of the Welsh Government and is laid before the National Assembly for Wales.

It was originally prepared and laid in accordance with Standing Order 26.6 in December 2012, and a revised Memorandum is now laid in accordance with Standing Order 26.28.

Member's Declaration

In my view the provisions of the Human Transplantation (Wales) Bill, introduced by the then Minister for Health and Social Services on 3 December 2012, are within the legislative competence of the National Assembly for Wales.

Mark Drakeford AM

Minister for Health and Social Services
Assembly Member in charge of the Bill

25 June 2013

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Description

1. The Human Transplantation (Wales) Bill prescribes how consent is to be given in Wales to the removal, storage and use of human organs and tissues for the purpose of transplantation. The Bill covers the donation of organs and tissues for transplantation both from deceased and living donors. In relation to deceased donation, it gives effect to the Welsh Government's commitment to introduce a soft opt-out system of organ and tissue donation in Wales. A soft opt-out system is one where consent to the removal and use of organs and tissues for transplantation is deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process. The overarching aim of the Bill is to increase the number of organs and tissues available for transplant, which will benefit the people of Wales by reducing the number of people dying whilst waiting for a suitable organ to become available and improving the lives of others.

2. The Bill sets out in one place the main provisions relating to consent for transplantation activities in Wales. However, in order to maintain an effective cross-border regime in terms of the operation of the UK-wide organ transplantation programme, there is an inevitable interplay with the Human Tissue Act 2004 (the 2004 Act), which is the current legislative framework for England, Wales and Northern Ireland. As a result, the Bill restates, for Wales, certain sections of the 2004 Act directly related to consent for the purposes of transplantation. However, certain other provisions of the 2004 Act not directly related to consent have not been restated but continue to apply in Wales, for example, provisions relating to the Human Tissue Authority (HTA) and sections 8, 33 and 34 of the 2004 Act. As described in paragraph 23, in most respects the Welsh Government has no intention of changing the settled law in this area; the main change brought about by the Bill is to introduce the concept of **deemed consent**.

Note on terminology used in this document

3. For ease of reading, where the terms "organs", "organ donation" or "donation" is used, this means "organ **and** tissue donation", unless the context suggests otherwise. Where the term "those closest to the deceased", "next of kin" or "family" is used, unless the context

suggests otherwise, means a person who stands in a "qualifying relationship"[1] to the deceased, as explained in the text.

Legislative background

4. The National Assembly for Wales has legislative competence to make provision relating to consent to the removal, storage and use of organs and tissues for the purpose of transplantation pursuant to Part 4 of the Government of Wales Act 2006. Subject 9 under the heading Health and Health Services of Schedule 7 to the Government of Wales Act 2006, is relevant in this context and is reproduced below.

Health and health services

9 Promotion of health. Prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder. Control of disease. Family planning. Provision of health services, including medical, dental, ophthalmic, pharmaceutical and ancillary services and facilities. Clinical governance and standards of health care. Organisation and funding of national health service.

Exceptions—

Abortion.

Human genetics, human fertilisation, human embryology, surrogacy arrangements.

Xenotransplantation.

Regulation of health professionals (including persons dispensing hearing aids).

Poisons.

Misuse of and dealing in drugs.

Human medicines and medicinal products, including authorisations for use and regulation of prices.

Standards for, and testing of, biological substances (that is, substances the purity or potency of which cannot be adequately tested by chemical means).

Vaccine damage payments.

Welfare foods.

[1] "Qualifying relationships" are set out at section 17(2) of the Bill: spouse, civil partner, partner, parent, child, brother, sister, grandparent, grandchild, child of a brother or sister, stepfather, stepmother, half brother, half sister and friend of longstanding.

Purpose and intended effect of the legislation

Issue

5. The shortage of human organs for the purposes of transplantation continues to cause unnecessary death and suffering, both to patients waiting for a transplant and their relatives. In 2011/12, according to NHS Blood and Transplant (NHSBT)[2], an England and Wales Special Health Authority, over 500 people died across the UK waiting for a transplant. In Wales, around three people a month died while waiting for an organ transplant in 2011/12. Around 300 people in Wales at any one time are on the active waiting list for a transplant.

6. Organ transplantation surgery is one of the most clinically effective forms of modern medical treatment and saves lives for patients with organ failure affecting heart, kidneys, lungs, pancreas and liver. Historically much of the focus has been on transplantation to save lives but recent years have also seen a number of transplants of tissue aimed not at saving lives but improving quality of life. Organ donation is also cost effective. One donor could save or improve the life of up to nine other people and many more can be helped through the donation of tissues. Organ donation helps reduce costs to the NHS, in particular in relation to kidney transplants.

7. Surveys consistently show a high level of support for the idea of organ donation[3, 4] and also reveal that the vast majority of people would be willing to accept an organ transplant[5]. However, this very high level of theoretical support is not borne out by the number of actual donations or by the proportion of people who have joined the NHS Organ Donor Register (ODR). Even taking into account the very welcome improvements in organ donor rates seen in Wales since 2008/09, there is still a considerable shortage of organs for those who need them.

8. It is important to make clear organ donation is only a possibility in a relatively small number of cases and in particular circumstances, normally where the deceased is on a ventilator in a hospital intensive care unit. To put this into context, over 30,000 people die in Wales every year, and in 2011/12 there were around 250 potential donors. However, only 67 of those people became organ

[2] NHSBT Transplant Activity in the UK Report for 2011/12.
[3] Barriers to Joining the Organ Donor Register 2003, RBA Research - on behalf of UK Transplant.
[4] Europeans and Organ Donation Report 2007, Special Eurobarometer, EU.
[5] Survey of 1975 people in the UK 2009, YouGov on behalf of NHS Blood and Transplant.

donors in Welsh hospitals. To maximise the number of donors, it is necessary to identify potential donors at the right point in the end of life clinical pathway and then approach relatives at the right time in order to talk about the deceased's wishes. This has been covered in guidance issued by NICE[6].

9. In accordance with the current law[7] and associated codes of practice, organ donation may only proceed with "appropriate consent". This currently means either:

   the donor having given express consent while they were alive, for example, by joining the ODR, or
   a nominated representative giving express consent after the person's death, or
   where the donor had given no instructions for or against, their next of kin being asked to give express consent on their behalf, based on what they think or know the deceased would have wanted.

10. According to figures provided to the Welsh Government by NHSBT, during 2011/12 only 37 per cent of people who donated organs in the UK had joined the ODR. For the remaining 63 per cent, the next of kin made the decision on their behalf.

11. Where next of kin are asked to give consent on behalf of the deceased under the current arrangements, they are in many instances reluctant to do so because they are unsure of what the deceased would have wanted. A number of barriers stop people taking active steps to join the ODR and/or telling their families their wishes, for example a reluctance to discuss death. The practical implication of this is that a person could agree with organ donation but, if they have not made this clear to their family members, the next of kin may not be sure of their view, and following their death do not agree to organ donation. The reverse is also true, where families agree to organ donation without knowing that the deceased would not have wanted to be a donor.

12. The effect of this Bill will be to introduce, for people over the age of 18 who both live and die in Wales[8], a concept called **deemed consent**. Deemed consent will exist alongside **express consent** as one of the ways in which a person can give their consent to the donation of organs for transplantation. People will be given the opportunity of taking an express decision, for example to formally "opt out" of organ donation by placing their name on a register. But

[6] National Institute for Health and Clinical Excellence: Organ Donation for Transplantation. December 2011.
[7] Human Tissue Act 2004 and Human Tissue Authority codes of practice 1 (Consent) and 2 (Donation of Solid Organs for Transplantation).
[8] The geographical demarcation of the Bill is based on where a transplantation activity takes place, but the practical effect is the same.

if they choose not to do so, despite having had the opportunity, then they will be treated as though they had no objection to being a donor (or in other words their consent will be deemed). Based on the experience of other countries in Europe with similar systems, we would hope to see an increase in the number of organs available for transplantation as a result.

Policy Background

13. In January 2008, following a comprehensive review of organ donation in the UK the Organ Donation Taskforce (ODTF) produced its report, *Organs for Transplants*[9]. The report made 14 recommendations aimed at improving the infrastructure and funding of organ donation, with a view to increasing organ donation rates by 50 per cent within five years. The report stated that in 2006, the UK had one of the lowest donation rates in the developed world with just under 13 deceased donors per million population (pmp). It also stated that nationally, the UK had a high rate of next of kin refusals, at 40 per cent. By contrast the ODTF report showed other developed countries had a much higher rate of donation (e.g. Spain 35 donors pmp, USA 27 donors pmp and France 23 donors pmp) and much lower rates of next of kin refusal (e.g. 20 per cent in Spain).

14. The Wales Organ Donation Implementation Group (WODIG) was set up to ensure the recommendations were implemented in Wales. Whilst supporting the recommendations made by the ODTF in its first report, the then Minister for Health and Social Services was of the view that they might not go far enough in terms of increasing donation rates, and as a result began a series of public debates in Wales during 2008 on whether the law relating to organ donation should be changed. These debates included consideration of various potential options for increasing the donation rate. These included:

[9] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122 .

mandated choice, whereby the population would be legally obliged to opt in or opt out or organ donation (either a voluntary or legally binding system)

hard opt-out systems, whereby organs would become available for donation after death if the deceased had not opted out, but where families would have little or no involvement in the decision

soft opt-out systems, where organs would become available for donation after death if the deceased had not opted out, but where families would retain full involvement in the process.

15. In November 2008, the ODTF looked at the potential impact of an opt-out system for organ donation in the UK and published its second report, *'The potential impact of an opt-out system for organ donation in the UK'*.[10] This report recommended against the introduction of an opt-out system at that time, preferring instead to concentrate effort on improvements to the current arrangements, but recommended reviewing the position after five years. The report also looked at mandated choice and hard opt-out systems as mentioned above, but discounted them because they believed such arrangements would pose formidable practical problems, would be difficult to enforce and be a fundamental departure away from UK norms.

16. Also in 2008, the then Health, Wellbeing and Local Government Committee of the National Assembly for Wales held an inquiry into presumed consent for organ donation, but recommended against the Assembly seeking legislative competence at that time. The Committee was of the view that the Welsh Government should first concentrate on taking forward the recommendations of the ODTF. However, the Committee did recommend that any consideration of legislation on presumed consent in the future should adopt a soft opt-out system where families are consulted. Although these reports ruled out a change in the law at that time, the results of consultations undertaken by the Welsh Government in 2008 and 2009 showed support amongst the Welsh public for a possible move towards an opt-out system for consent. This has been reinforced by the BBC/ICM 2012 St David's Day poll of 1,000 people[11] which suggested that nearly two thirds of Welsh people are in favour of such a change. A Public Attitudes Survey published by the Welsh Government[12] shows there is still a similar level of

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[10] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312.

[11] http://www.bbc.co.uk/news/uk-wales-politics-17226610

[12] http://wales.gov.uk/about/aboutresearch/social/latestresearch/publicattitudesorgandonation/?lang=en

support for a change in the law, as well as a growing awareness of the Welsh Government's proposals.

17. As a result of work undertaken by WODIG and its counterparts in the other UK countries, together with increased publicity about organ donation, there have been improvements since the first ODTF report. Since 2008, according to NHSBT figures, organ donation rates have increased by just over 34 per cent across England and Wales. In Wales there has been particular success, with a 49 per cent increase in deceased organ donors in Welsh hospitals between 2007/08 and 2011/12[13]. However, NHSBT figures provided to the Welsh Government show the UK as a whole still has a relatively low donation rate with 16.4 pmp (2010 figures) compared with 32 pmp in Spain, 30.7 pmp in Croatia and 30.2 in Portugal[14].

18. Despite these improvements, in Wales there are still around 300 people at any one time on the active waiting list for a transplant and 41 Welsh residents died in 2011/12 while waiting for a transplant. There is also concern that there are limits to how much more can be achieved by doing more of the same, and fears that the gap between the number of donors and those requiring a transplant will grow if further intervention is not considered. Whilst there is of course much work underway to improve overall health, the ageing population, medical advances and people living longer with chronic conditions are factors which suggest that demand for organs for transplantation will grow rather than diminish in future.

19. The Welsh Government is committed to improving the rates of donation in Wales and is of the view that this will be achieved through the introduction of a soft opt-out system of consent to organ donation. The Welsh Government has considered the evidence relating to alternative methods for increasing consent to donation, many of which have been considered by numerous committees and which have been debated in public. However, these other options were discounted at an early stage. For example, further efforts in relation to increasing consent rates as part of the current opt-in system, whilst no doubt capable of delivering incremental increases, are unlikely either to achieve a breakthrough in public attitudes and awareness or to ultimately lead to a significant increase in the consent rate. Other options are either impractical to implement and enforce (i.e. mandated choice) or culturally unacceptable to the public (i.e. hard opt-out system). There is also insufficient international evidence to show they will have the desired effect. It therefore believes that the time has come to make a change in the law to introduce a soft opt-out system, together with an extensive communication and education programme

[13] NHSBT figures.
[14] NHSBT figures.

encouraging people to make a decision and to ensure their families know their wishes. This will increase the number of organs available for transplantation and create a change in society in Wales where agreeing to organ and tissue donation becomes the norm rather than the exception. Introducing a soft opt-out system should narrow the gap between the numbers of people who say that they would be willing to donate an organ and those who actually do become donors.

20. It is not intended to alter the way in which organs and tissues are collected or allocated, and existing arrangements with NHSBT will continue. This means 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. Welsh residents have benefited from being part of the UK-wide arrangements for many years and there are no plans to alter this as we introduce the new arrangements for consent to donation in Wales. Currently the organs[15] and tissues donated are in respect of organs, the kidney, heart, liver, lungs, pancreas and the small bowel and for tissues bone, skin, tendons, meniscus, heart valves and vessels, eyes and, infrequently, trachea. In practice current opt in arrangements **do not** cover novel forms of transplantation such as face or limb transplants. Nor, in law, do they cover the use of foetal or reproductive tissues. The Bill now provides the Welsh Ministers with a power to make regulations setting out which organs will be excluded from the new deemed consent arrangements. The Secretary of State has agreed in principle to make an order pursuant to section 150 of the Government of Wales Act 2006, amending Section 1 of the 2004 Act. This will allow organs and tissues retrieved under deemed consent in Wales to be used for transplantation in England and Northern Ireland.

Objectives

21. The principal aim of the legislation is to increase the number of organ donors through the introduction of a soft opt-out system. This will in turn allow more organ transplants to take place which will prevent unnecessary deaths and improve the quality of life for more people. Evidence[16] suggests that introducing an opt-out type system could result in a 25 to 30 per cent increase in deceased organ donation rates which could equate to a further 15 donors each year in Wales, each of whom (based on figures shown in NHSBT's 2010/11 Activity Report) on average might donate 3 organs. This means around 45 more organs could become available to the UK pool for transplantation.

[15] An organ is defined in existing regulations as "a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy".

[16] Abadie A, Gay G, The impact of presumed consent legislation on cadaveric organ donation: A cross-country study, Journal of Health Economics, 2006.

22. The Bill prescribes how consent is to be given in Wales to the removal, storage and use of parts of a body of a deceased person for the purpose of transplantation. The Bill covers the donation of organs and tissues for transplantation both from deceased and living donors. In terms of deceased donors, consent can take the form of either deemed or express consent and covers all aspects of the process, including any preparations that are required prior to death in accordance with existing ethical and legal guidelines.

23. Some provisions of the 2004 Act relating to consent to transplantation activities, have been restated in the Bill, with some modifications. With the exception of deemed consent applying in Wales, the Welsh Government has no intention of changing the settled law in these areas.

Residency

24. Where a person dies in Wales in circumstances which make them a potential donor, in order to know how to proceed in terms of consent, it will be necessary to establish where they lived. The soft opt-out system will only apply to those people who live in and die in Wales[17], who have had enough time to understand the law and have had an opportunity to opt out, if that is their wish. Deemed consent therefore applies to all people over the age of 18, 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 12 months before they died and who die in Wales. A period of 12 months is felt to be enough time for people to become aware of the deemed consent arrangements and to take action to opt out if that is their wish. Both the initial and ongoing communications arrangements will be frequent enough so as to ensure people are aware of the law applicable in Wales. The legislation does not expressly exclude any category of person on the grounds of residency, e.g. people studying in Wales at a university or people visiting or working in Wales for 12 months or more. Whether individuals are considered to be resident in Wales will depend on certain criteria being met, and will also be a matter for discussion with those closest to them, after death.

25. Whether a person is living in Wales needs to be clear and easy to determine from the viewpoint of the public and the NHS. The term “ordinarily resident” has been used in the Bill but is not defined. This is because ordinarily resident status needs to be assessed and is primarily a question of degree and fact. The concept means a person’s abode in a particular place or country which has been adopted voluntarily and for settled purpose and part of the regular

[17] As referred to above this is the practical effect of the legislation, though the law applies by reference to where a transplantation activity takes place.

order of life for the time being, whether of short or long duration. A settled purpose could include education, business, employment, health or family. All that is necessary is that the purpose of living in a place has a sufficient degree of continuity to be properly described as settled, and apart from accidental or temporary absences. In practice, a person must satisfy each criterion of a three stage test in order for the provisions of section 4 of the Bill to apply to them. The criteria are:

whether the person's current address is in Wales;
whether the person normally lives at that address for the majority of the time; and
whether the person has lived at that address (or another address in Wales) for at least 12 months before they died.

26. For the first point above, an address will be treated as being in Wales if it falls within the area of a Welsh local authority. There is a widely used system for address searches which will be used so as to avoid any doubt about the person residing in Wales. It will not solely depend on the postcode, as in border areas postcodes do not always follow the Wales-England border, although the postcode would be part of the identifier. Nor will it depend on the location of the GP with whom a patient was registered. We have also considered the use of the 22 electoral registers in Wales and it does not appear that they can provide definitive evidence of residence. However we will keep this under review.

27. In the majority of cases it should be straightforward to find evidence that the other two requirements are satisfied, from medical records and conversations with the next of kin. However, there may be some cases where it is not so easy to determine whether a person lives in Wales. As a safeguard, whether a person satisfies the criteria of all elements of the three stage "test" will be checked in discussion with the next of kin. If it cannot be demonstrated that all three criteria are met, the person may not be safely assumed to be ordinarily resident in Wales, and consent will not be deemed to be given. In these situations, organ donation can still be discussed, but the express consent of a person in a qualifying relationship will be sought instead.

Registration of wishes – general

28. The next issue to determine would be whether the person had expressed a wish in relation to organ donation. The Welsh Government realises that security and accuracy of the information in relation to a person's wishes is of paramount importance and these principles will underpin the development of the system used for the new arrangements. How the wishes of individuals who live in Wales are likely to be recorded is covered under the Detailed Implementation and Delivery Plan at paragraphs 56 to 71. There

will be a new register system capturing either a person's wish to donate, or a wish not to donate. The system will need to be able to link with register arrangements for the rest of the UK to ensure no wishes are missed – for example, if a person moved to Wales but had not got round to registering with a GP. It will also need to work the other way round, for people moving out of Wales. The new register will also record details of appointed representatives. It will also be important for the system to be able to ensure no-one has registered a conflicting wish. A review commissioned by the Welsh Government in 2012 suggested that the best way of achieving all these requirements would be a comprehensive redevelopment of the ODR, to meet the legislative needs of all parts of the UK in an integrated way. This approach will minimise the risks of error into the future. The redevelopment of the ODR has been agreed between the UK Government, the Welsh Government, the Scottish Government and Northern Ireland Executive. It has also been agreed in principle that the Welsh Government will contribute 50% of the cost of the redevelopment of the ODR, with the remaining 50% shared between the other UK administrations. This is reflected in the Regulatory Impact Assessment within this Explanatory Memorandum.

Consent - adults

29. In the case of adults who live in Wales, the default position will be for consent to be deemed to have been given for a transplantation activity done in Wales unless:

    CASE 1: the person is still alive, in which case their express consent is required – this covers living donation (e.g. of a kidney);

    CASE 2: the person has died and had expressed a wish – either to be a donor or not to be a donor; or

    CASE 3: the person has appointed a representative(s) to deal with the issue of consent to donation.

30. It is important to highlight that in Case 3, if the appointed person(s) is unable to give consent, for example if they cannot be contacted, then the patient's consent will not be deemed. In such instances, Case 4 will apply and the decision to consent would pass to the qualifying relations in a ranked list.

31. The new law therefore makes deemed consent the default position for adults who live and die in Wales, unless any of the above cases apply. Consent will not be being deemed in isolation, but within the context of a very wide ranging communications campaign which is described in further detail below. In effect, adults living in Wales for at least 12 months will be presented with a choice of three actions:

to take no action (the default position, in which case consent will be deemed to have been given); to express a wish to be a donor (opt in) or to express a wish not to be a donor (opt out). People who wish to record a wish one way or the other will be able to do so via arrangements which will be made for a register. There are, however two further qualifications to this. The first involves relatives or friends of long standing being able to object on the basis that they knew the deceased would not have consented. This is covered in section 4(4) of the Bill. Further discussion of the role of the next of kin for adults is set out at paragraphs 41 to 44 below. The second is that the transplantation activity involves material of a type specified by Welsh Ministers in regulations.

32. Clearly it is essential in a system where consent is deemed to have been given, for people to have had ample opportunity to express their objection, if that is their wish. This underlines the need for public education. There is also a need to promote organ donation more generally. Section 2 of the Bill places Welsh Ministers not only under a general duty to promote transplantation in order to improve the health of the people of Wales, but also under a more specific duty to ensure people are aware of the arrangements for deemed consent. In practice, this will include information about how to register a wish. This duty underpins an extensive publicity and engagement campaign forming part of the implementation of the new legislation and beyond. Placing the requirement on the face of the legislation will ensure that there is ongoing publicity about the arrangements for the benefit of people moving to and leaving Wales, and for people who reach the age of 18.

Consent – children

33. The deemed consent system applies to people over the age of 18 and will not apply to children and young people. However, the Bill does not alter the ability of a person under the age of 18 (referred to here as children or young people) to express, during their lifetime, a wish to be a donor or not to be a donor. The proposals will allow children and young people to use the new register arrangements to record their wish.

34. In practice, if a child or young person dies in circumstances where donation becomes a possibility, then their wish to consent to, or not consent to, organ donation will be made known to their family as part of the discussion on organ donation. It would be normal practice for a person with parental responsibility to be consulted to establish whether the child was “Gillick” competent to make the decision. This means the child should have had sufficient maturity to have been able to understand the nature and consequences of their decision. Where a child or young person has not expressed a wish to donate or not to donate, then their consent will not be deemed to have been given and the person with parental

responsibility or in a qualifying relationship will be asked to make the decision about organ donation.

35. Young people living in Wales who are approaching their 18th birthday will be identified through NHS systems and contacted six months beforehand. They will be told about the arrangements that will apply to them from the age of 18 – i.e. that unless they have expressed a wish not to be an organ donor, their consent will be deemed to have been given. They will be given enough time to decide whether or not they want to opt out. Young people who have already expressed a wish to be a donor or not to be a donor will be reminded of their decision and advised they need take no further action, unless they wish to change their mind.

People who lack capacity

36. The Mental Capacity Act 2005 confirms that a person must be assumed to have capacity to make decisions unless it is established otherwise. It is recognised that people may have the mental capacity to make decisions about some aspects of their lives but not others; that some people may never have the mental capacity to make that decision; that some may lose their mental capacity, and for others mental capacity may fluctuate.

37. The Bill does not alter the current ability of any person to express, during their lifetime, a wish to donate their organs or not to donate. People will be able to use the new register arrangements to express a wish. In doing so, and as happens now, mental capacity will not be questioned.

38. Every effort should be made to facilitate those lacking capacity to understand the new law and to make a decision in the light of it. This emphasis on facilitation during a person's lifetime will form part of our communications programme. At the time of death, if organ donation is a possibility, then in a similar situation to that described for children and young people, the deceased's wishes will be made known to their family as part of the discussion about organ donation. Where a person who lacked capacity had not expressed a wish for or against donation, their consent will not be deemed to be given since, if there is doubt as to whether they had capacity with regard to understanding the notion that consent can be deemed, this could make such consent invalid. The Bill provides that an adult who has died would have had to lack capacity for a sufficiently long period before dying so as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed. It is also recognised that capacity can fluctuate and therefore the arrangements need to be flexible rather than overly prescriptive in the legislation. A discussion with the person's family in which these issues are sensitively addressed, together with a review of the medical records, will therefore be the most practical

method of determining whether someone lacked capacity for the requisite period. This will not constitute a formal assessment of someone's mental capacity, but a judgement reached in discussion with those closest to the deceased. We would envisage the relevant HTA code of practice covering such matters. Where it is felt after discussion with family that a person did not have capacity to understand that consent could be deemed, then a person in a qualifying relationship will be asked to make the decision about organ donation.

Excepted adults

39. The arrangements for deemed consent will **not** apply to any of the following people, who are regarded as excepted adults under the legislation; i.e. those who:

    have not been ordinarily resident in Wales for at least 12 months prior to death;
    lack capacity to understand that consent could be deemed in the absence of express consent (see above).

40. The categories of people who may be excluded by virtue of their residency status, e.g. prisoners, are not prescribed, since circumstances vary widely and will need to be assessed. Individuals will be safeguarded as discussions with the deceased's family will determine whether or not they ordinarily reside in Wales. It is for this reason that, in practice, people who cannot be identified and/or whose next of kin cannot be contacted will not be subject to deemed consent, since it will not be possible to satisfy the residency and other requirements in those cases without family being present.

Role of family and friends of long standing under the deemed consent arrangements

41. As happens today, it is essential to involve next of kin in any situation where organ donation may be a possibility. This is because, for safety and quality reasons, it is very rare for donation to go ahead without their input. The only real exception is for people who have given their consent by joining the ODR but who have no family. In that situation, NHS staff may perform a risk assessment in order to decide if donation can go ahead. It is important to clear up any misunderstandings about who makes the final decision about donation. Under the current system, legally, the wishes of the deceased (where they are known) have precedence. The only time the next of kin can make the decision under the current arrangements is when the wishes of the deceased are not known. In practice, families are presented with information about

organ donation, including whether the deceased person had expressed a wish, and asked whether they are prepared to agree to donation taking place.

42. Under the new arrangements families will continue to have an involvement in the process at a practical level, as the next of kin will still be asked to confirm details about the deceased's health and lifestyle which might not be contained in their medical records and which could affect their suitability as a donor. When it comes to giving consent to organ donation, it is for the deceased to decide whether to opt in, opt out or have their consent deemed – the wishes of the deceased are paramount. The wishes of the deceased, whether it be through deemed or express consent should be made known to the family by NHS staff as part of the discussions. In the case of deemed consent case, the legislation provides relatives or friends of long standing with the right to object if they know the deceased would not have consented.

43. Telling close family about your wishes relating to organ donation will be one of the key messages of the education campaign which will accompany the new legislation, since uncertainty about what their relative would have wanted is what prevents many families engaging with the organ donation process. This then results in healthy organs being lost to a potential recipient.

44. To assist with understanding the effect of the Bill in relation to the role of the next of kin, various scenarios relating to adults who live and die in Wales, are set out below. The scenarios do not cover the question of mental capacity nor what happens in the case of children, as these have been explained in paragraphs 33 to 38:

A: Where the deceased does not register any wishes in relation to donation (the default position) and their consent is deemed: In this situation, the deceased's consent to donation will be deemed because they had the opportunity to express a wish not to be a donor (opt-out) but did not do so. However, section 4(4) of the Bill provides that a relative or friend will be able to object on the basis that they know the deceased person would not have consented. For example, the deceased may have discussed the matter with them and expressed a view to the effect that they did not want to be an organ donor. The information given by the relative or friend in objecting should be sufficient to lead a reasonable person to conclude they knew the deceased would not have consented. It is not the intention to prescribe the type and quality of information which will fulfill this requirement, since this will be a matter of judgement in each individual case. This will be covered further in the HTA code of practice.

Where a relative or friend does not object by producing such information about the wishes of the deceased, then they will be in the

position of knowing the deceased had not opted out, and had made no further wishes known. In these cases, the default position is that the deceased was in favour of donation and, as a matter of law, the deceased's consent is deemed. However, this does not mean organ donation will automatically proceed as there will then be a discussion with the family about the donation process, including the medical history of the deceased. Clinical teams also have a responsibility to be sensitive to the views and beliefs of the surviving relatives in accordance with good practice guidance. This means clinical teams would not add to the distress of families. It is important to be clear, however, that families do not have a legal veto because the law will recognise the deemed consent of the deceased as having precedence.

Consideration has been given to whether the relatives or friends able to object to deemed consent should be from a limited list and ranked in order to prevent disagreements within families. However, it is considered that any relative or friend of long standing should be able to make this objection on the basis of the views of the deceased, as it is the quality of the information provided which is most important, rather than who provides it.. The only time that relationships are ranked is when express consent is to be given, on behalf of a child or an excepted adult, or if an appointed representative is unable to act.

B: Where the deceased registers a decision to be a donor (opts in): In this situation, the deceased has given express consent to donation of some or all of their organs and, as happens now when someone has joined the ODR, the next of kin will be made aware of these wishes and this will form part of the discussions about organ donation. Considerations about being sensitive to the views and beliefs of the surviving relatives are the same as described above, as is the fact that legally, the wishes of the deceased have precedence. If organ donation did not go ahead against the express wishes of the deceased, we are considering the potential for the next of kin being asked to sign a form to the effect that they understood the position, which is similar to the current position in Scotland.

C: Where the deceased registers a decision not to be a donor (opts out): In this situation, the deceased has expressed a wish not to donate that must be accepted. Families will be advised that their relative had opted out and that organ donation therefore is not possible. Only if the next of kin produces a written change of mind, signed by the deceased and post-dating their wish not to be a donor held on the register, could this be accepted as the consent of the deceased which was in force immediately before they died. In these circumstances donation might be considered. It is also likely that next of kin would be asked to sign a form to the effect that they understood the position.

Adults living outside Wales but who die in Wales

45. People who die in Wales (meaning that a transplantation activity would take place in Wales) but who do not ordinarily live in Wales will **not** be subject to the deemed consent arrangements.

46. In all situations, the deceased's address details will be checked as described in paragraphs 25 to 27. Where the record shows the deceased does not live in Wales and it is confirmed with the next of kin that he or she lived in England, Scotland or Northern Ireland, the ODR would be checked. Where the person is on the ODR, this means the deceased has given express consent to donation of some or all their organs and this will be made known to the family and form part of the discussion about organ donation.

47. If they are not on the ODR, or they are not UK residents, then the next of kin would be asked whether they are prepared to give their express consent to donation.

Adults who die in Wales but who have not lived in Wales for long enough

48. Where the record shows the deceased lived in Wales, but conversations with the family reveal that he or she has done so for less than 12 months, then their consent will **not** be deemed because the Bill requires that they must have been ordinarily resident in Wales for at least 12 months prior to death for that provision to apply. The register will still be checked to see if the person had recorded a wish in the meantime.

49. Where the person is shown as an organ donor on the register this will be made known to the family and form part of the discussion about organ donation.

50. If the person has already expressed a wish not to be a donor on the register, then their family would be advised and organ donation would not go ahead, as in 44C above. If they are not on the register at all, then the next of kin would be asked whether they are prepared to give their consent to donation.

People living in Wales who die in England, Scotland or Northern Ireland

51. If a Welsh resident dies in hospital in England or Northern Ireland the existing provisions of the 2004 Act would apply. If a Welsh resident dies in Scotland, then the existing provisions of the Human Tissue (Scotland) Act 2006 will apply. However, it will be important for NHS staff in England, Scotland and Northern Ireland to be aware of the arrangements in Wales and to check through the new register arrangements whether the person had expressed a wish either to donate, or not to donate their organs and tissues. This is because decisions taken in Wales under the new legislation will be

equally valid under the legislation in operation in the other UK countries. Where a Welsh resident dies in England, Scotland or Northern Ireland and they have not expressed any wish in relation to organ donation, it will not be possible to deem their consent as having been given as it would be if they died in Wales. In such cases, the next of kin would be asked whether they are prepared to consent to donation.

People who move away from Wales

52. It is possible that a person could move out of Wales, leaving their opt-out decision on the register. This means NHS staff across the UK will need to be aware of the law in Wales and the process will need to ensure such staff are alerted to any recorded decision made whilst the person lived in Wales. This is because a stated wish to donate or not to donate will still have effect under the legislation covering other parts of the UK, even if the person no longer lives in Wales.

Use of organs for transplantation

53. It is the intention that organs donated in Wales under deemed consent will be allocated for transplantation on a UK wide basis. The Secretary of State has agreed in principle to make an order amending section 1 of the 2004 Act so that organs retrieved under deemed consent in Wales can be used lawfully in England and Northern Ireland.

54. It will also be the case that organs donated in England or elsewhere will be able to come into Wales for transplantation (currently, for solid organs, only kidney and pancreas transplants are undertaken in Wales, at the University Hospital of Wales. All other organ transplants for Welsh residents, i.e. heart, liver, lung, etc. are carried out in England).

Guidance

55. Guidance relating to the provisions of the Bill will be set out in the codes of practice prepared by the responsible authority (currently the HTA). The code(s) will be subject to the approval of both the Welsh Ministers and the National Assembly for Wales under the affirmative procedure. The Bill sets out this provision at sections 14 and 15. Officials in the Department for Health and Social Services are working with counterparts at the HTA in relation to the format and content of the code(s) and a working draft has been provided to the National Assembly for Wales Health and Social Care Committee.

Detailed Implementation and Delivery Plan

Timescales for implementation

56. Timescales for the introduction of the Bill are shown after paragraph 76. In terms of the implementation of the new arrangements, there will be a two year minimum lead-in time from the date the Bill receives Royal Assent in 2013 to the Act coming in to force in 2015. This is necessary to ensure that a public awareness campaign, as outlined below, is undertaken on a large scale to make people aware of the legislation and the choices available to them, and for robust systems to be developed to capture the wishes of citizens correctly and securely.

Communicating with the public

57. Section 2 of the Bill places Welsh Ministers under a duty to provide information and increase awareness about transplantation, including about the arrangements for deemed consent. An extensive publicity and engagement campaign will form part of the implementation of the new legislation and beyond. The Minister gave a commitment during Stage 2 proceedings to amend the Bill to place a duty on Welsh Ministers to carry out public awareness activities at least once every 12 months, and to consider whether a report should be made annually to the Assembly on those activities.

58. A detailed Communications Strategy has been developed to deliver the public awareness campaign required. This covers an initial five year communications campaign to publicise the introduction of the legislation and to explain the choices that will be available to the Welsh population. The strategy recognises that it is essential to target different audiences and all sectors of the community.

59. The Communications Strategy sets out four phases for the awareness campaign. As the implementation of the legislation approaches, the communication activity will intensify. A fifth phase has also been identified for long term communication requirements that will need to remain in place long after the Act comes into force.

60. Below is a table that illustrates the timing of the different communications phases, an overview of the activity and a broad outline of the likely communication methods that will be used. However it is important to stress that the communication methods and messages will be thoroughly tested in advance with a representative sample of the population to ensure their effectiveness. This research may mean the communication methods outlined below may be adapted to ensure the public awareness and engagement campaign is as effective as possible.

61. It is also important to note that the communications activity will be measured for its effectiveness on a regular basis throughout the five year campaign. This will test the population's awareness, understanding and attitudes towards the legislation. The survey is a representative sample of approximately 1,000 people and a core set of questions will be asked each time. We will therefore be able track changes or shifts in perceptions and adapt the communications strategy accordingly. The first wave of the research (the baseline) was undertaken in June 2012, prior to the publication of the Draft Bill and published on the Welsh Government website on 19 October 2012. The second wave will commence in June 2013.

Period	Activity Overview	Possible Communication Methods
Until Royal Assent	*Seeding* Seeding the benefits of the legislation alongside gradually educating people on the general process of organ donation, as well as encouraging more people to join the ODR.	Public Relations: Regular pro-active UK, Wales-wide and regional media activity to ensure awareness of legislative process as well as the importance of organ donation. Recent PR has focused on real experiences from a range of people to help illustrate the impact of transplantation. Direct Engagement: A programme of direct engagement with BME communities and Faith groups across Wales has been ongoing to not only raise awareness on the legislation but to also inform the development of accessible information. Other 'hard to reach' groups have been identified and ongoing engagement with representative organisations also continues to ensure awareness among these groups is achieved. This work will be ongoing over the 5 years. Public information road shows have also been an effective one-to-one engagement tool to promote the ODR, dispel organ donation myths, discuss specific detail of the legislation and answer questions from members of the public. Information about the legislation is available via the Welsh Government Website www.wales.gov.uk/organdonation www.cymru.gov.uk/rhoiorganau Research and Development: Development and testing of the creative materials for the major campaign which will go live post Royal Assent.

Post Royal Assent – date to be confirmed	*Announcement* A short phase to announce the law has been passed, an implementation period will commence alongside a two year public awareness campaign.	In addition to previous phase, the following methods will be added; Public Relations: A planned PR campaign to set out how the new system will be implemented, timescales for the public and the action they will need to take when the systems are in place. This will not just cover Welsh media but also UK wide. Online information: Launch of a dedicated website for organ donation in Wales, which will be used as one of the main 'calls to action' throughout the campaign as a point for individuals to gain further information about the legislation. Stakeholders: Joint activity with stakeholders to explain the implementation process. Working with stakeholders that represent hard to reach groups of people will be particularly important to ensure that those who do not access traditional media are alerted to the proposed changes. School: Information to young people through schools / education system.
Announcement to Implementation	*Information* The information phase will provide communications on what exactly people need to do. It will provide people with more detailed information and the media will be chosen to maximise opportunities for people to dwell and digest. This will comprise several periods of advertising in multiple media and with increasing intensity. The communication periods will be at regular intervals and last several weeks.	In addition to the methods used in previous phases paid-for advertising will be added to help guarantee coverage for the new law. Paid-for advertising: May include regional press, commercial radio, online/digital, outdoor advertising including buses and ambient media. The advertising will take place over 2 years with 3-4 major periods of activity. The initial period will include awareness messages so that people are aware that the law will change. Advertising periods 3 or 4 will change to include details on how people can register their wishes in advance of the implementation. The timing of the advertising is likely to be as follows:

		Advertising period1 (4-6 months after announcement) Advertising period 2 (6 months later) Advertising period 3 (6months later) Advertising period 4 (Month before implementation) Non-paid for advertising: Information distributed via partnerships with local authorities, NHS organisations, faith groups and other stakeholders that will help us reach those who may not see/hear/access traditional media. Resources will be available via the dedicated website for partners, and stakeholders to access in a range of accessible formats and languages Public Relations including roadshows and social media activity will be ongoing. Direct engagement with a range of communities and stakeholders will continue during this time to ensure we reach as wide an audience as possible (Young people, students, older people, disabled people, prisoners, BME communities, people who are on the margins of society). Direct Mailing: It is important that we reach every household in Wales. In addition to the advertising the other way to guarantee this is to send an information leaflet directly to every household across Wales. This will happen in either period 3 or 4. Following implementation of the new system it will be important to issue a reminder mailer to serve as a 'mop up' for those who may have accidentally discarded or lost the first, or to remind those who took no action following receipt of the first.
At Implementation and 6 months after implementation	*Legislation Implementation* As soon as the new system is implemented the communications and advertising will switch messages to ensure everyone realises the new opt-out system is	The public information campaign will continue with the same intensity for the first 4-8 wks to ensure people know how to register their wishes and to ensure people know the new system has been implemented. Methods will continue as above. As time progresses, the campaign will slowly

	operational.	reduce in intensity and serve as an ongoing reminder through communication methods that have longevity such as poster sites in GPs hospital settings, pharmacies, outdoor advertising. Public Relations will continue through UK, Welsh and regional media. Some advertising options may continue for up to 6 months and others may be more long term.
Long term	*Reminder* This aim of this phase will be to provide more long term communication, undertaken on a 6 monthly basis.	As above methods will be chosen with longevity for maximum exposure such as poster distribution through local authorities and through NHS settings. Some paid for advertising poster sites may also be used on a regular basis. The following options will be investigated for regular, long term information to help reach new residents and those who turn 18 years old: School curriculum opportunities GP registrations both for new registrants and alerts for those who approach their 18th birthday. Universities and colleges in Wales NUS Emails via UCAS to all university students who choose to study in Wales Local Authorities – regular mailings such as council tax bills Information via Estate Agents in Wales Information distributed through major employers for new recruits from outside Wales Information via Armed Forces

Registration of wishes - detail

62. The following paragraphs set out the principles of how we intend to record the wishes of individuals. The overriding intention is to have a system which is:

safe,
secure,

reliable,
maintainable and
flexible enough to cope with normal population movements.

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63. There will be a single register system capturing whether a person has expressed a wish for or against donation.

64. The new register system will also be able to record “partial” decisions, i.e. if someone only wants to donate some but not all of their organs. People who decide not to express a wish for or against donation will not be included on the register.

65. A review of registration systems in 2012 recommended that the best approach for developing new register arrangements would be to redevelop the ODR so that it can provide both its existing functions for people outside Wales, and provide the opportunity for people in Wales to opt-out. This has now been agreed between the Welsh Government, the UK Government, and the devolved administrations of Scotland and Northern Ireland. The system will allow a person who lives in Wales to record a wish not to be a donor (an opt-out). Please see paragraph 52 above for people who move away from Wales.

66. Redeveloping the ODR in an integrated way will minimise the risks of holding contradictory records on an individual by maintaining only one database containing a single record for each person who has expressed a view in relation to donation. The new register arrangements will be maintained by NHSBT who currently manage the existing ODR. Discussions are continuing with the other UK administrations on the detailed functions of the new register.

67. Given that under the existing legislation a recorded wish not to consent to organ donation has legal status, the new register for Welsh individuals will need to be accessible whether a person died in Wales or elsewhere in the UK. The Privacy Impact Assessment at Appendix 7 of the Regulatory Impact Assessment sets out how data will be accessed. In due course, a Data Protection Policy and Fair Processing Notice will be developed.

68. As a minimum the register will capture the following details, however it is important to stress that only information needed for the purpose will be held:

Name;
Address;
Date of birth;
NHS number; and
the expressed wish of the individual for or against donating some or all of their organs.

Explanation of how people will register a wish under the new system

69. Under the current system it is possible to record a wish to donate organs in a number of ways including via the Driver and Vehicle Licensing Authority (DVLA) and via the Boots' Advantage Card scheme. There is also a direct link from Facebook to the ODR web pages. These partnerships will continue to provide individuals with the opportunity to record their wish to become a donor but will not be altered for the time being to allow individuals to express a wish not to be a donor. Direct online registration of wishes will be available, and there will also be forms and telephone assistance for those who do not wish to use the internet. All of the registration mechanisms will be available in English and Welsh and meet best practice for accessibility.

When people will be able to start registering their wishes

70. Until the new legislation comes into force in 2015, registration of a wish to donate should continue, via the current arrangements for the ODR. The Welsh Government will continue to actively support efforts to encourage individuals to join the ODR and share their views with their families. Consideration is being given to how the choice made by Welsh residents who have joined the ODR will be treated under the new arrangements.

71. Before, and in readiness for, activation of the deemed consent system, the opt-out wishes of people living in Wales will be captured.

Risk if legislation is not made

72. If this legislation is not made, the introduction of a soft opt-out system for organ donation in Wales will not go ahead. This puts at risk the increase in the number of organ donors we expect to see delivered as a result of the proposals. Fewer people will benefit and lives that might otherwise have been saved, or improved, will not be.

How the legislation will enable sectors to operate more efficiently

73. The legislation sets out the arrangements for consent to transplantation activities in Wales. This will increase the number of organs available for transplantation, saving lives and improving the health of the population. The Regulatory Impact Assessment sets out clearly the overall cost benefits.

How the legislation will improve outcomes for disadvantaged or excluded sections of society

74. Our communications strategy will target disadvantaged or excluded sections of society to help them understand the new legislation, and know how they can register their wishes if they want to. We recognise this will need specific action to reach excluded sections of society working with existing representative groups, support systems and networks.

75. For people from Black and Ethnic Minority (BME) groups there is a particular prospect of improving outcomes. In these communities there is a shortage of suitable organs and a lack of donors who could provide a better clinical match. As a result proportionately more people from BME communities are waiting for a transplant. The legislation should increase donation rates and benefit these sectors of society who are disadvantaged in the current system.

Territorial extent

76. This Bill applies in relation to consent where a transplantation activity takes place in Wales. It applies across all of Wales, and does not just affect certain parts of Wales.

Timescales for legislation

The expected timescales are as follows:

Introduction of Bill into Assembly	December 2012
Royal Assent and commencement of communication provisions in Section 2, together with Sections 1, 19 and 20	Late Summer 2013
Consultation on relevant secondary legislation under the Bill	During the two years prior to main provisions coming into force in 2015
Commencement of remaining provisions	At least two years following Royal Assent
Code of Practice: Development and consultation; approval by the Welsh Ministers and laid for approval before the Assembly	Likely to be completed within a year of Royal Assent
Development of new register arrangements	Development complete 9 months before commencement.
Public awareness campaign	From Royal Assent in 2013 onwards; peaking 6 months prior to main provisions coming into force in 2015; continuing thereafter and indefinitely

Consultation

77. There has been a significant amount of engagement and consultation with the public and stakeholders on this issue since 2008. The then Minister for Health and Social Services launched public debates on organ donation in Wales between October 2008 and January 2009. This included a series of public meetings across Wales, including an inter-faith meeting and took account of written views and a telephone survey.

78. This public engagement confirmed support for increasing organ donation rates. A wide range of suggestions were put forward on how this may be achieved, including possible changes to the law to in relation to consent for organ donation.

79. In May 2009, the Welsh Government published a consultation paper '*Options for changes to the organ donation system in Wales'*. The result of the consultation showed strong public support for a change in the law to introduce a soft opt-out system of organ donation in Wales.

80. With this support, the First Minister announced the inclusion of a Legislative Competence Order (LCO) in the 2010/11 Legislative Programme. An LCO to extend the legislative competence of the Assembly in relation to consent or other authorisation for organ and tissue donation for the purposes of transplantation was laid in the Assembly in January 2011. The National Assembly for Wales' Legislation Committee No.1, with responsibility for scrutiny of the LCO, launched a public consultation on the Order on 12 January 2011. However, following a "yes" vote to the referendum for additional law making powers on 3 March 2011, the then Minister for Health and Social Services made a statement to plenary on 9 March 2011 advising that she had withdrawn the LCO and acknowledged that it was for the next Government to introduce an Assembly Bill.

81. The Welsh Labour Manifesto for the May 2011 elections contained a commitment to introduce a soft opt-out system for organ and tissue donation in Wales. A similar commitment was also contained in other party manifestos. Following the return of a Labour-led Welsh Government, in his legislative statement of 12 July 2011 the First Minister committed the Welsh Government to *"provide for an opt-out system of organ donation, backed by a comprehensive communication programme".*

82. A White Paper followed, setting out the Welsh Government's intention to legislate on this matter. Entitled '*Proposals for Legislation on Organ and Tissue Donation',* the White Paper was

published for a twelve week public consultation period between 7 November 2011 and 31 January 2012. It outlined the broad principles the Welsh Government would follow in bringing forward the policy and sought views on how the arrangements should work in practice. A total of 1,234 responses were received.

83. During the consultation period Welsh Government officials held a series of 13 public meetings across Wales to explain the current process, answer questions on how the proposals would work and to listen to the views of attendees. A total of 166 people attended the meetings. Furthermore, eight meetings with key stakeholders were held during the consultation period: three meetings with the NHS in Wales and meetings with Specialist Nurses and Clinical Leads on Organ Donation, Professional Bodies, the Voluntary Sector and representatives from faith groups. These meetings considered the details of the policy proposals contained in the White Paper and focused in particular on the practical arrangements around the implementation of the policy, namely:

    the need for clarity surrounding the role of the next of kin;
    determining Welsh residency; and
    critical care capacity.

84. The Welsh Government's report on the Consultation Summary was published on 8 March 2012 and all the responses were put on the website on 18 April.[18] The summary report included details of the organisations notified of the White Paper consultation and a list of respondents.

85. The White Paper consultation document did not invite comments on whether to introduce a new system, but rather how to go about doing so. However, a large proportion of the responses, 91 per cent, set out opinions on the principle of the proposed legislation. 52 per cent of all respondents supported the introduction of a soft opt-out system and 39 per cent were opposed.

86. In addition, Beaufort Research Ltd was commissioned by the Welsh Government to undertake a series of Focus Groups to support the formal consultation exercise. The researchers held six focus groups across Wales and carried out seven in-depth interviews in order to explore attitudes towards organ donation and the proposals for legislation. Those participating in the focus groups represented a range of ages and a number from Black and Minority Ethnic communities. The research showed broad support for organ donation amongst the focus group participants. Generally, people found it easier to argue for our opt-out proposals than against. Whilst this was qualitative research with a small sample, it was consistent with wider surveys of opinion.

[18] http://wales.gov.uk/consultations/healthsocialcare/organ/?lang=en

87. At the same time the research illustrated the importance of raising awareness of the organ donation process in general and also of the proposals for a soft opt-out system.

88. A further consultation on a draft Bill and Explanatory Memorandum took place between 18 June and 10 September 2012 and a total of almost 3,000 responses were received, the vast majority of which took the form of a standard letter expressing concerns about the legislation. During the consultation period seven stakeholder meetings were held across Wales, which were also open to members of the public. The consultation responses highlighted a number of key issues which required further clarification or explanation, including the role of family members, explanations about brain death and other concerns about diagnosis of death, as well as more detailed points on the drafting of the Bill. Some of the issues have been addressed further in this Explanatory Memorandum, whilst others will be looked at as part of the Communications Strategy. A Consultation Summary report was published on 19 October 2012[19] and all the responses will be published on the Welsh Government website.

89. The results of a representative survey of the public in Wales were published at the same time as the most recent consultation report[20], showing there is a still a broad level of support for a change in the law with almost half those asked saying they were in favour, with under a quarter saying they are against. As well as this, the survey shows a relatively high level of awareness of the Welsh Government's proposals to legislate in this area, with 58 per cent saying they had heard something about the changes.

How the responses to the consultation have helped shape the legislation

90. 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.

Power to make subordinate legislation

91. The Bill contains provisions to make subordinate legislation. The table below sets out in relation to each provision:

[19] http://wales.gov.uk/consultations/healthsocialcare/organbill/?lang=en&status=closed
[20] See footnote 12.

the person upon whom, or the body upon which, the power is conferred;
the form in which the power is to be exercised;
the appropriateness of the delegated power;
the applied procedure (affirmative, negative, no procedure) if any.

Summary of powers to make subordinate legislation

Section	Power conferred on	Form	Appropriateness of delegated power	Procedure	Reason for procedure
4(5)	Welsh Ministers	Regulations	Considered to be appropriate as this relates to operational detail	Super-affirmative	Sensitivity of the subject matter
7(10)(b)	Welsh Ministers	Regulations	Considered to be appropriate as this relates to operational detail	Super-Affirmative	Sensitivity of the subject matter
8(2)	Welsh Ministers	Regulations	Considered to be appropriate as this relates to operational detail	Super-Affirmative	Sensitivity of the subject matter
14(3)(f)	Welsh Ministers	Order	Considered to be appropriate as this relates to operational detail	Super-Affirmative	Sensitivity of the subject matter
17(4)	Welsh Ministers	Order	Considered to be appropriate as this relates to operational detail	Super-Affirmative	Sensitivity of the subject matter
19(1)	Welsh Ministers	Order	Considered to be appropriate as this relates to	No process	Commencement

Regulatory Impact Assessment (RIA)

92. A Regulatory Impact Assessment has been completed in accordance with Standing Order 26.6(vi) for the Bill and follows at Part 2.

PART 2

Regulatory Impact Assessment

93. This Regulatory Impact Assessment (RIA) appraises the impact of the Welsh Government's draft Human Transplantation (Wales) Bill. It is found that the benefits associated with an increase of one donor per year more than offset costs incurred. It includes an Equality Impact Assessment and Privacy Impact Assessment as appendices.

Options

94. The Explanatory Memorandum makes clear at paragraphs 14, 15 and 19 that potential alternatives for increasing the consent rate to donation, such as mandated choice and hard opt out systems were considered during the policy development, but discounted. One policy option is therefore considered to be capable of meeting the policy intention: to introduce a soft opt-out system of deceased organ and tissue donation in Wales. A soft opt-out system is one where consent to the removal and use of organs and tissues for transplantation is deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process. The overarching aim of the policy is to increase the number of organs and tissues available for transplant, which will benefit the people of Wales by reducing the number of people dying whilst waiting for a suitable organ to become available and improving the lives of others.

95. The purpose of the RIA is to establish the impact of the proposed change against a 'do nothing' base line. In this case, the 'do nothing' baseline is to continue with the current opt-in system and carry on implementing the recommendations of the Organ Donation Task Force (ODTF).

96. Establishing the 'do-nothing' base line or the counterfactual is complicated because it is highly uncertain how many organs will become available over the next several years under the current system. This is because the current system is evolving owing to the implementation of the ODTF recommendations. Therefore, it is not appropriate to establish the counterfactual by extrapolating from any previously established patterns or trends.

Evidence Base to Establish Impact of Proposed Legislation

97. Public opinion in Wales supports the adoption of a soft opt-out system of organ donation. A BBC sponsored poll conducted earlier this year found that 63% of respondents were "*in favour of a law*

that presumes consent for organ donation." A similar result was found from a more recent Public Attitudes Survey commissioned by the Welsh Government[21]

98. In its report on the potential impact of an opt-out system being introduced in the UK, the ODTF found: "*in working with the public we found that the majority – around 60% – would support a change to an opt out system, as long as it was properly implemented to ensure that the rights of vulnerable groups were protected and there was sufficient information to back it up. This is consistent with previous surveys carried out by others*"[22]

99. Survey work undertaken by the European Commission found that 63% of respondents in the UK answered "*yes*" to the question: "*If you were asked in a hospital to donate an organ from a deceased close family member, would you agree?*"[23]

100. Overall then, survey evidence suggests there is potential for an opt-out system to improve organ donation rates.

101. Secondary research shows that a wide range of factors impinge on donation rates including the organ donation system(s) itself as well as cultural and psychological considerations.

102. Differing outcomes across countries with similar organ donation systems testifies to the myriad of factors that can impact on donation rates. For example, an opt-out system is operated in Spain and it has the highest donation rate in the world with approximately 32 deceased donors per million population. Greece also operates an opt-out system and it has a low donation rate: approximately 4 deceased donors per million population[24].

103. Abadie and Gay[25] suggested that opt-out systems can improve organ donation rates and suggest donation rates in countries with opt-out type systems can be 25 to 30 per cent higher compared with countries where other systems are in operation.

104. In a comprehensive review of the effect of opt-out systems on organ donation, the University of York reviewed Abadie and Gay's study; found it to be robust and noted it as a study with no major methodological flaw.[26] Several other studies and survey evidence

[21] See footnotes 11 and 12.

[22] See footnote 10.
[23] Key facts and figures on EU organ donation and transplantation, Council of Europe, Directorate-General for Health and Consumers, 2007.
[24] NHSBT figures.
[25] See footnote 16.
[26] Rithalia A, McDaid C, Suekarran S, Norman G, Myers L, Sowden A. A systematic review of presumed consent systems for deceased organ donation. *Health Technol Assess* 2009;**13**(26).

were also reviewed with the overall picture suggesting opt-out systems are associated with improved donation outcomes.

105. The University of York review which was undertaken on behalf of the ODTF, provides a balanced summary of the nuanced backdrop against which the Welsh Government proposes to introduce legislation for an opt-out system. The conclusions are quoted in full in the box below.

"1) Presumed consent alone is unlikely to explain the variation in organ donation rates between different countries. A combination of legislation, availability of donors, transplantation system organisation and infrastructure, wealth and investment in healthcare, as well as underlying public attitudes to and awareness of organ donation and transplantation may all play a role, although their relative importance is unclear. The between country comparison studies overall point to presumed consent law being associated with increased organ donation rates (even when other factors are accounted for) though it cannot be inferred from this that the introduction of presumed consent legislation per se leads to an increase in donation rates. The before and after studies suggest an increase in donation rates following the introduction of presumed consent legislation, however it is not possible to rule out the influence of other factors on donation rates.

2) It is important to note that the survey evidence is incomplete and the variation in attitudes between surveys may reflect differences in methods and the phrasing of questions. Some surveys suggest a lack of public support for presumed consent, both in the UK and in other countries. However, more recent UK surveys provide evidence of support for presumed consent."[27]

106. Overall then, it is clear that on the basis of available evidence, changing to an opt-out system of organ donation in Wales is much more likely than not to result in an increase in donation and transplantation rates. It is also the case that we cannot be definite about the magnitude of any increase that is likely to occur, partly because of the changes currently being introduced to the current opt-in system (the 'do nothing' option), and because the purpose of the RIA is to establish the impact of the proposed legislation against the 'do nothing' option.

107. However, it is feasible to outline costs and benefits that would result from a range of changes in donation/transplantation rates that could result from changing the current opt-in system to a soft opt-out system of organ donation.

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[27] See footnote 26.

108. Such an approach makes it possible to estimate the number of additional organs that would be required to justify the costs incurred by introducing a soft opt-out system in Wales.

109. Owing to the lack of precision regarding changes in organ donation numbers that may occur as a result of introducing an opt-out system, it is imperative that the impact of the proposed legislation is monitored and evaluated. It will be particularly useful to compare changes in organ donations in Wales with England as the opt-in system will be retained in England for the foreseeable future. Proposals for evaluation are set out in the Post-Implementation Review at Appendix 5.

110. Paragraphs 111-119 describe the costs and benefits that will likely be associated with introducing an opt-out system of organ donation. The costs and benefits of the option are assessed against the baseline option of 'do nothing'. The appraisal period considered is 10-years with costs and benefits discounted using the central HM Treasury discount rate of 3.5% except when estimating the 'quality adjusted life year' (QALY) benefits. The discount rate used for QALYs is 1.5% as recommended by the UK Department of Health (see Appendix 3 for explanation of QALYs).

Costs and benefits

Costs of a soft opt-out System

111. Two broad categories of costs have been identified. First, costs to set up and maintain the infrastructure required to operate a soft opt-out system of organ donation will be incurred. Such costs include business and system changes, the processing of opt-out requests, public communications, and evaluation. Discounted over ten years, the costs are approximately £7.5 million and are listed in Appendix 1. These costs will be borne by the Welsh Government. Some of these ongoing 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.

112. The second category of costs refers to those that will be incurred when organs are retrieved from deceased people and transplanted. These are variable costs and will differ by organ type. For the RIA, the most common organs to be transplanted - namely kidneys, livers, hearts and lungs - are considered. This approach is viewed as appropriately proportionate. Details are shown in Appendices 2a – 2d as follows:

The cost of a kidney transplant is £50,000 at 2011/12 prices, and there is a follow-up cost each subsequent year of £8,000. Each year there is a saving in kidney dialysis avoided of £28,000.

The total pre-surgery and surgery costs of a liver transplant are £59,000 at 2011/12 prices; in the first two years of follow-up there is an annual cost of £12,000 and thereafter annual follow-up costs of £5,000. Each year there is a saving in medical management avoided of £22,000.

The cost of a heart transplant in the first year is £147,000 at 2011/12 prices, and there is a follow-up cost each subsequent year of £12,000. Each year there is a saving in medical management avoided of £5,000.

The cost of a lung transplant in the first year is £156,000 at 2011/12 prices, and the follow-up costs in years 2, 3, 4 and 5 are £22,000, £9,000, £8,000 and £4,000 respectively. In the first year there is a saving in medical management avoided of £18,000 and in the second year £13,000.

These 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. For illustration, the average number of transplants anticipated from 15 additional donors would be approximately 26 kidneys, 10 livers, 2 hearts and 4 lungs.

113. The activity and costs associated with an increased number of donors will be managed within current NHS resources. The NHS should, through its arrangements to fund specialised services, similarly meet the costs of an increased number of transplantation procedures.

Benefits of a soft opt-out system

114. Patients who receive transplants on average benefit from extended life and an improvement in quality of life as compared with patents whose conditions are treated with medical management.

115. Quality of life improvements are captured by QALYs, where a year of perfect health is worth 1 QALY and valued at £60,000 (see Appendix 3 for further explanation of QALYs). QALYs also capture life extension benefits.

116. Research undertaken by the UK Department of Health in the mid 2000s estimated the number of QALYS that result from organ

transplantation[28]. These assumptions have been used for this RIA and are detailed in Appendices 2a – 2d.

117. A second category of benefits from organ donation result from the savings made from transplanted patients not having their conditions managed medically. Medical management savings were estimated by the UK Department of Health in the mid 2000s[29]. These savings, up-rated for inflation in the interim, have been used for the purposes of this RIA and are included as benefits.

118. The costs associated with kidney, liver, heart and lung transplants only have been considered. To estimate benefits, the same approach has been taken. It is recognised that other organs and tissues are transplanted. However, we are satisfied that the bulk of benefits are captured by restricting the analyses to kidneys, livers, hearts and lungs.

119. It is recognised that it is highly likely that a large proportion 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. However, the Welsh Government attaches the same value to an additional organ transplanted irrespective of where in the UK that transplant takes place. Accordingly, benefits are assessed at a UK level but are subjected to sensitivity analysis (see paragraphs 125 - 132).

Net Impact of a Soft Opt-Out System

120. Costs and benefits that would result from one **additional** kidney, liver, heart and lung transplant per year are set out in Appendices 2a – 2d.

121. It is not prudent at this juncture to attach a probability to any particular change in organ donation rates that may result from adopting a soft opt-out system.

122. Based on the assumptions set out in Appendices 1 and 2a – 2d, it is clear that only a small increase in donor numbers and an associated increase in transplants would generate substantial benefits. For example, an increase of one **additional** donor **each** year with associated increases in organ transplantations discounted over a ten year period has an estimated net present value (NPV) of approximately £3 million.

[28] The Department of Health used a number of sources to estimate QALYs gained from transplantation and shared this information with Welsh Government economists in 2009.

[29] See footnote 28.

123. Appendix 2e sets out the NPVs that would result from a range of changes in donation and transplantation rates that could result from the Welsh Government adopting a soft opt-out system.

124. It is instructive to note the impact that would result if the increase in donation rates of 25-30 per cent that Abadie and Gay[30] found to be associated with the introduction of opt-out systems occurred in Wales. An increase of 25 per cent from a base of 65 donors (this is the number of Welsh residents who died in Wales and donated organs in 2011/12) would be equivalent to approximately 15 additional donors. 15 additional donors with associated increases in transplantation rates would generate an NPV of approximately £147 million.

Sensitivity Analysis

125. Based on the assumptions set out in Appendices 1 and 2a - 2d, an increase of one donor per year with associated increases in organ transplantations, would generate sufficient benefits for a soft opt-out system to more than pay for itself.

126. This result is sensitive to the assumptions underpinning the analysis. Therefore, it is appropriate to vary some of the assumptions underpinning the analysis and establish how results vary in response.

127. Results are especially sensitive to the monetary value attached to a QALY. The UK Department of Health attach a monetary value of £60,000 to a QALY[31], an assumption we have adopted for this RIA. However, there is debate within academic and medical fields as to the appropriate value to attach to a QALY. Accordingly, it is sensible to reduce the value of a QALY and note how that impacts on the net benefits generated by any change in organ donation that may result from introducing an opt-out system of organ donation.

128. In Appendix 4 we show how the value of organ donation changes using different assumptions for the value of a QALY. 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'.

129. It was stated in paragraph 119 that benefits are assessed at a UK level noting that a proportion of any additional organ transplants would occur outside Wales. Figures provided to the Welsh Government by NHSBT shows that over a 4 year period (2008-

[30] See footnote 16.
[31] Quantifying health impacts of government policies, A how-to guide to quantifying the health impacts of government policies, Department of Health, 2010.

2011) just over 30 per cent of organs donated by people in Wales are transplanted into people living in Wales.

130. If we calculate benefits on a Wales only basis (i.e. we claim just 30 per cent), then that would reduce the value of the benefits we can attribute to an increase in organ donation numbers that could result from introducing an opt-out system. Equally, apportioning benefits in this way also reduces any negative impacts that would result should donation numbers fall. Calculating benefits and costs in this way has a minor impact on the number of donors needed for an opt-out system to 'break-even'. With this scenario, an increase of between one and two **additional** donors **each** year with associated increases in organ transplantations would still allow for an opt-out system to 'break even' (see Appendix 4).

131. There is uncertainty too as regards the costs of establishing and operating an opt-out system of organ donation; labelled fixed costs in Appendix 1. In the base case total fixed costs are estimated at £8 million discounted over ten years. Of the various fixed cost items detailed in Appendix 1, the greatest uncertainty is in system development costs (or IT changes). These costs total £2.5 million approximately.

132. If system costs were 100% higher than estimated in the base case and allowing for some slippage in other costs, total fixed costs would increase to £10 million. In such circumstances, the NPV of one additional donor **each** year with associated increases in organ transplantations discounted over a ten year period has an estimated net present value (NPV) of £0.3 million compared with £3 million in the base case. Discounted fixed costs would have to be approximately £2.7 million (approximately 36%) more than in the base case to push the NPV down to zero. Accordingly, it is reasonable to conclude that the results recorded in the base case scenario are robust to higher fixed costs.

Costs to Welsh Government

133. The Welsh Government will assume the costs associated with the infrastructure changes required to operate a soft opt-out system of organ donation, together with public communication costs, training/delivery costs, and evaluation. These costs will be met from the Delivery of Targeted NHS Services Action within the Health and Social Services Main Expenditure Group. The costs are set out at Appendix 1.

Costs on Other Bodies, Individuals and Businesses

134. The intention of introducing a soft opt-out system is to increase the number of organs available, potentially by some 25 per cent. The unpredictable nature of organ donation, even under the current

arrangements, means that systems must, to an extent, be in a state of readiness to act quickly and to deal with peaks and troughs. This flexibility is built into the existing acute care system and organ donation activity is not separately costed. A 25 per cent increase in the number of organ donors translates to 15 additional actual donors per annum, or just over one additional donor per month. In terms of impact on critical care, surgical services including theatre time and staffing costs, we therefore believe the predicted increase will incur no additional costs. In relation to the taking of consent to donation, and the retrieval and transportation of organs these are provided for as part of the Welsh Government funding to NHS Blood and Transplant which is calculated on a population basis. The current funding is £2.88 million per annum, which is recurrent. Once again, we are of the view that the number of additional donors we are anticipating will incur no additional costs.

Impact on Small Businesses

135. There will not be any direct impacts on small businesses.

Impact on Voluntary Sector

136. There will not be any direct impacts on the voluntary sector.

Equality Impact Assessment

137. An Equality Impact Assessment is at Appendix 6. This includes a statement that the Welsh Ministers have taken due regard of the UN Convention of the Rights of the Child.

Privacy Impact Assessment

138. A Privacy Impact Assessment is at Appendix 7.

Sustainable Development Impact

139. There are no direct implications for sustainable development.

Competition Assessment

140. There will not be any direct impacts on competition.

Post implementation review

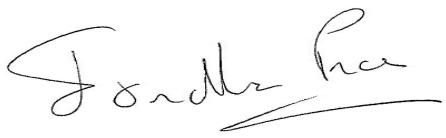
141. In light of the particular difficulty establishing the impact of the proposed legislation on organ donation rates, it is imperative that the impact of the proposed legislation is monitored in a rigorous fashion at frequent intervals. A post implementation review has been planned and details are set out in Appendix 5.

Chief Economist's Statement

I am satisfied that the costs and benefits that would result from changes in organ donation rates in Wales leading to changes in the numbers of organs transplanted in patients in the UK have been reasonably and proportionately estimated in this Regulatory Impact Assessment.

Establishing the counterfactual against which to assess the potential impact of legislation to move to an opt-out system is complex in light of changes being implemented to the current opt-in system. As a result the baseline is highly unpredictable. It is quite clear that the public in Wales would prefer an opt-out system, even though there is a lack of primary survey evidence capturing specifically how people will respond to opt-out legislation. Overall the evidence base suggests that it is reasonable to expect opt-out legislation will improve donation rates, although it is not sensible at this juncture to attach probabilities to specific outcomes.

For these reasons, impacts are described in a "what if" or scenarios fashion. The lack of specificity regarding potential outcomes means that it is imperative that the impact of the proposed legislation is monitored and evaluated in a rigorous manner.



Jonathan Price
Chief Economist
Welsh Government
June 2013

RIA Appendix 1

Fixed Costs Expected with Adoption of Organ Opt-Out System

	£000s										***(Discount Rate =3.5%)***
	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	**Total Fixed Cost**
Communications	£143	£383	£808	£2,215	£150	£150	£150	£150	£150	£150	£3,986
Management of business change	£91	£182	£273	£40							£557
IT changes	£134	£1,124	£553	£156	£156	£156	£156	£156			£2,394
Other nation register contributions		-£653	-£413	-£98							-£1,105
Receive and process additional registrations			£419	£328	£81	£81	£81	£81			£955
Notify 17 year olds				£25	£50	£50	£50	£50	£50	£50	£263
Evaluation	£27	£65	£50	£0	£95						£219
Clinician training			£224	£100							£300
Total	£395	£1,101	£1,915	£2,766	£532	£437	£437	£437	£200	£200	£7,569

Assumptions for Kidney Analysis

Median Survival time for transplanted patients	13 years
Median survival time for patients on dialysis	11 years
Increase in QALYs gained from transplant (see Note 1 below table).	4
Monetary value of one QALY	£60,000
Cost of Transplant Surgery (in 11/12 prices)	£50,000
Annual cost of follow up for kidney transplant patients	£8,000
Annual cost of kidney dialysis	£28,000

Note 1: The number of QALYs gained from a transplant is calculated by comparing the health state of a transplant patient with the health of a patient receiving dialysis on a number of dimensions such as mobility, lack of pain/discomfort, ability to self-care, anxiety/depression and capacity to carry out 'usual activities'. A year of 'perfect' health is worth 1 QALY. Drawing on a number of sources, the UK Department of Health has estimated that, on average, a transplant kidney patient enjoys better health over 13 years of life that is equivalent to 4 QALYs as compared with a patient treated by dialysis[32].

Note 2: Costs were estimated by the UK Department of Health in 2005/2006 prices[33]. To account for inflation since then, the costs were up-rated using the GDP deflator.

[32] See footnote 28
[33] See footnote 28

Annual Distribution of Costs and Benefits for 1 Additional Kidney Transplant per Year

(£000s)

Year	A Transplant Related Costs	B QALY Benefits	C Savings Against Dialysis	Net Benefit (B+C-A)
0	£152	£240	£306	£394
1	£152	£240	£306	£394
2	£152	£240	£306	£394
3	£152	£240	£306	£394
4	£152	£240	£306	£394
5	£152	£240	£306	£394
6	£152	£240	£306	£394
7	£152	£240	£306	£394
8	£152	£240	£306	£394
9	£152	£240	£306	£394
NPV (Discount rate = 3.5% except for QALYs = 1.5%)	£1,307	£2,066	£2,633	£3,392

Note 1: Transplant related costs and savings against dialysis were calculated by the UK Department of Health in 2006. These assumptions have been used for the RIA; up-rated for inflation by the GDP deflator[34].

Note 2: Transplant costs and benefits have been valued on a discrete, rather than on a continuous basis. So, for example, one additional kidney transplant patient in year zero (the year of the first additional transplant) will generate costs of £152,000 over 13 years of expected survival. One additional kidney transplant patient in year one will generate the same costs and so on for one additional transplant in each of years 2 - 9. Costs are then discounted over the 10 year appraisal period. The same approach was used to estimate QALY benefits and savings against dialysis[35].

[34] See footnote 28.

[35] This approach mirrors the approach taken by the UK Department of Health. See the following link for example: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_111386 .

RIA Appendix 2b

Assumptions for Liver Analysis

Survival time for transplanted patients	18 years
Median survival time for patients on medical management	1.5 years
Increase in QALYs gained from transplant (see Note 1 below table).	13
Monetary value of one QALY	£60,000
Cost of assessment	£9,000
Cost of candidacy	£7,000
Cost of liver transplant surgery	£43,000
Annual cost of follow-up for 1st two years	£12,000
Annual cost of follow-up for 3rd & subsequent years	£5,000
Annual cost of medical management	£22,000

Note 1: The number of QALYs gained from a transplant is calculated by comparing the health state of a transplant patient with the health of a patient whose liver condition is medically managed on a number of dimensions such as mobility, lack of pain/discomfort, ability to self-care, anxiety/depression and capacity to carry out 'usual activities'. A year of 'perfect' health is worth 1 QALY. Drawing on a number of sources, the UK Department of Health estimated that on average, a liver transplant patient enjoys better health over 18 years of life that is equivalent to 13 QALYs as compared with a patient whose condition is treated by medical management[36].

Note 2: Costs were estimated by the UK Department of Health in 2005/2006 prices[37]. To account for inflation since then, the costs were up-rated using the GDP deflator.

[36] See footnote 28.
[37] See footnote 28.

Annual Distribution of Costs and Benefits for 1 Additional Liver Transplant per Year (£000s)

Year	A Transplant Related Costs	B QALY Benefits	C Savings Against Medical Management	Net Benefit (B+C-A)
0	£159	£780	£33	£653
1	£159	£780	£33	£653
2	£159	£780	£33	£653
3	£159	£780	£33	£653
4	£159	£780	£33	£653
5	£159	£780	£33	£653
6	£159	£780	£33	£653
7	£159	£780	£33	£653
8	£159	£780	£33	£653
9	£159	£780	£33	£653
NPV (Discount rate = 3.5% except for QALYs = 1.5%)	£1,372	£6,714	£282	£5,624

Note 1: Transplant related costs and savings against medical management were calculated by the UK Department of Health in 2006[38]. These assumptions have been used for the RIA; up-rated for inflation by the GDP deflator.

Note 2: Transplant costs and benefits have been valued on a discrete, rather than on a continuous basis. So, for example, one additional liver transplant patient in year zero (the year of the first additional transplant) will generate costs of £159,000 over 18 years of expected survival. One additional liver transplant patient in year one will generate the same costs and so on for one additional transplant in each of years 2 – 9. Costs are then discounted over the 10 year appraisal period. The same approach was used to estimate QALY benefits and savings against medical management.

[38] See footnote 28.

RIA Appendix 2c

Assumptions for Heart Analysis

Median Survival time for transplanted patients	10 years
Median survival time for patients on medical management	4 years
Increase in QALYs gained from transplant (see Note 1 below table)	7
Monetary value of one QALY	£60,000
Cost of 1st year including surgery	£147,000
Annual cost of follow-up	£12,000
Annual cost of medical management	£5,000

Note 1: The number of QALYs gained from a transplant is calculated by comparing the health state of a transplanted patient with the health of a patient whose heart condition is medically managed on a number of dimensions such as mobility, lack of pain/discomfort, ability to self-care, anxiety/depression and capacity to carry out 'usual activities'. A year of 'perfect' health is worth 1 QALY. Drawing on a number of sources, the UK Department of Health estimated that on average, a heart transplant patient enjoys better health over 10 years of life that is equivalent to 7 QALYs as compared with a patient whose condition is treated by medical management[39].

Note 2: Costs were estimated by the UK Department of Health in 2005/2006 prices[40]. To account for inflation since then, the costs were up-rated using the GDP deflator.

[39] See footnote 28.
[40] See footnote 28.

Annual Distribution of Costs and Benefits for 1 Additional Heart Transplant per Year (£000s)

Year	A Transplant Related Costs	B QALY Benefits	C Savings Against Medical Management	Net Benefit (B+C-A)
0	£159	£420	£22	£283
1	£159	£420	£22	£283
2	£159	£420	£22	£283
3	£159	£420	£22	£283
4	£159	£420	£22	£283
5	£159	£420	£22	£283
6	£159	£420	£22	£283
7	£159	£420	£22	£283
8	£159	£420	£22	£283
9	£159	£420	£22	£283
NPV (Discount rate = 3.5% except for QALYs = 1.5%)	£1,369	£3,615	£188	£2,434

Note 1: Transplant related costs and savings against medical management were calculated by the UK Department of Health in 2006[41]. These assumptions have been used for the RIA; up-rated for inflation by the GDP deflator.

Note 2: Transplant costs and benefits have been valued on a discrete, rather than on a continuous basis. So, for example, one additional heart transplant patient in year zero (the year of the first additional transplant) will generate costs of £159,000 over 10 years of expected survival. One additional heart transplant patient in year one will generate the same costs and so on for one additional transplant in each of years 2 - 9. Costs are then discounted over the 10 year appraisal period. The same approach was used to estimate QALY benefits and savings against medical management.

[41] See footnote 28.

RIA Appendix 2d

Assumptions for Lung Analysis

Median Survival time for transplanted patients	5.5 years
Median survival time for patients on medical management	2 years
Increase in QALYs gained from transplant (see Note 1 below table).	4
Monetary value of one QALY	£60,000
Cost of 1st year including surgery	£156,000
Cost of follow-up in year 2	£22,000
Cost of follow-up in year 3	£9,000
Cost of follow-up in year 4	£8,000
Cost of follow-up in year 5	£4,000
Annual cost of medical management in year 1	£18,000
Annual cost of medical management in year 2	£13,000

Note 1: The number of QALYs gained from a transplant is calculated by comparing the health state of a transplant patient with the health of a patient whose lung condition is medically managed on a number of dimensions such as mobility, lack of pain/discomfort, ability to self-care, anxiety/depression and capacity to carry out 'usual activities'. A year of 'perfect' health is worth 1 QALY. Drawing on a number of sources, the UK Department of Health estimated that on average, a lung transplant patient enjoys better health over 5.5 years of life that is equivalent to 4 QALYs as compared with a patient whose condition is treated by medical management[42].

Note 2: Costs were estimated by the UK Department of Health in 2005/2006 prices[43]. To account for inflation since then, the costs were up-rated using the GDP deflator.

[42] See footnote 28.
[43] See footnote 28.

Annual Distribution of Costs and Benefits for 1 Additional Lung Transplant per Year (£000s)

Year	A Transplant Related Costs	B QALY Benefits	C Savings Against Medical Management	Net Benefit (B+C-A)
0	£196	£240	£32	£75
1	£196	£240	£32	£75
2	£196	£240	£32	£75
3	£196	£240	£32	£75
4	£196	£240	£32	£75
5	£196	£240	£32	£75
6	£196	£240	£32	£75
7	£196	£240	£32	£75
8	£196	£240	£32	£75
9	£196	£240	£32	£75
NPV (Discount rate = 3.5% except for QALYs = 1.5%)	£1,689	£2,066	£273	£650

Note 1: Transplant related costs and savings against medical management were calculated by the UK Department of Health in 2006[44]. These assumptions have been used for the RIA; up-rated for inflation by the GDP deflator.

Note 2: Transplant costs and benefits have been valued on a discrete, rather than on a continuous basis. So, for example, one additional lung transplant patient in year zero (the year of the first additional transplant) will generate costs of £196,000 over 5.5 years of expected survival. One additional lung transplant patient in year one will generate the same costs and so on for one additional transplant in each of years 2 - 9. Costs are then discounted over the 10 year appraisal period. The same approach was used to estimate QALY benefits and savings against medical management.

[44] See footnote 28.

Summary of Costs and Benefits from Adopting an Organ Donation Opt-Out System

Summary Of Impacts Of Possible Outcomes From Introduction of Soft Opt-Out System Of Organ Donation

Scenarios for Change in Donor Numbers p.a.	Change No. *Kidney* Transplants p.a.	Change No. *Liver* Transplants p.a.	Change No. *Heart* Transplants p.a.	Change No. *Lung* Transplants p.a.	Value of Change in *Kidney* Transplants £Mils	Value of Change in *Liver* Transplants £Mils	Value of Change in *Heart* Transplants £Mils	Value of Change in *Lung* Transplants £Mils	Value of Change in *Organ* Transplants £Mils	ODR Fixed Cost £Mils	Net Present Value of Change in Transplants £Mils
0	0.00	0.00	0.00	0.00	£0	£0	£0	£0	£0	£8	-£8
1	1.76	0.67	0.14	0.29	£6	£4	£0	£0	£10	£8	£3
2	3.52	1.34	0.29	0.58	£12	£8	£1	£0	£21	£8	£13
3	5.28	2.01	0.43	0.86	£18	£11	£1	£1	£31	£8	£23
4	7.05	2.69	0.57	1.15	£24	£15	£1	£1	£41	£8	£34
5	8.81	3.36	0.71	1.44	£30	£19	£2	£1	£51	£8	£44
10	17.62	6.72	1.43	2.88	£60	£38	£3	£2	£103	£8	£95
15	26.42	10.07	2.14	4.32	£90	£57	£5	£3	£154	£8	£147
20	35.23	13.43	2.86	5.76	£120	£76	£7	£4	£206	£8	£198
25	44.04	16.79	3.57	7.20	£149	£94	£9	£5	£257	£8	£250
-1	-1.76	-0.67	-0.14	-0.29	-£6	-£4	-£0	-£0	-£10	£8	-£18
-2	-3.52	-1.34	-0.29	-0.58	-£12	-£8	-£1	-£0	-£21	£8	-£28
-3	-5.28	-2.01	-0.43	-0.86	-£18	-£11	-£1	-£1	-£31	£8	-£38
-4	-7.05	-2.69	-0.57	-1.15	-£24	-£15	-£1	-£1	-£41	£8	-£49
-5	-8.81	-3.36	-0.71	-1.44	-£30	-£19	-£2	-£1	-£51	£8	-£59
-10	-17.62	-6.72	-1.43	-2.88	-£60	-£38	-£3	-£2	-£103	£8	-£110
-15	-26.42	-10.07	-2.14	-4.32	-£90	-£57	-£5	-£3	-£154	£8	-£162
-20	-35.23	-13.43	-2.86	-5.76	-£120	-£76	-£7	-£4	-£206	£8	-£213
-25	-44.04	-16.79	-3.57	-7.20	-£149	-£94	-£9	-£5	-£257	£8	-£265

Note 1: The number of organ transplants that can be expected under different assumptions for organ donor numbers have been calculated using data averaged over the last five years. For example, between 2006 and 2011, 1.76 kidneys were transplanted from each organ donor. It is assumed that each additional organ donor will result in 1.76 kidney transplants.

Note 2: Values are rounded to the nearest million.

Quality-Adjusted-Life-Years (QALYs)

The concept of QALYs is well documented and is widely used as an input in allocating scarce resources in health services funded by the public sector. Typically health policies are designed to prolong and improve life. QALYs combine both aspects into a single measure.

The UK Department of Health describe QALYs as follows: "*The measure Quality Adjusted Life Year ("QALY") allows the health impact on both life years and quality of life to be expressed in a single measure. The QALY approach weights life years (saved or lost) by the quality of life experienced in those years. Years of good health are more desirable than years of poor health. Poor health is described in terms of the mix of effects on the individual. This mix may include, for example, not only pain and disability but also other dimensions such as anxiety or the ability to carry out usual activities. All these different dimensions are then summarised in a weight, which is applied for the duration of the poor health or until death.*[45]

In the mid 2000s, the UK Department of Health, drawing on a number of evidence sources[46], calculated QALYs for different types of organ transplants. We used these estimates in 2009 when undertaking a cost-benefit analysis of services provided by NHS Blood and Transplant. We liaised with UK Department of Health economists at that time. For this RIA, it was considered reasonable and appropriate to use the DOH assumptions again. The assumptions on QALYs gained from organs transplantation are outlined in appendices 2a – 2d.

The UK Department of Health estimates that a QALY has a monetised value of £60,000[47].

[45] See footnote 31.
[46] See footnote 28.
[47] See footnote 31.

Sensitivity Analysis

Value of Net Impact of Changes in Organ Donation Numbers Using Different Assumptions for QALYs

Scenarios for Change in Donor Numbers p.a.	Scenarios for QALY Value								
	£60,000	£55,000	£50,000	£45,000	£40,000	£35,000	£30,000	£25,000	£20,000
	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils
0	-£8	-£8	-£8	-£8	-£8	-£8	-£8	-£8	-£8
1	£3	£2	£1	£0	-£0	-£1	-£2	-£3	-£3
2	£13	£11	£10	£8	£7	£5	£4	£2	£1
3	£23	£21	£19	£16	£14	£12	£9	£7	£5
4	£34	£30	£27	£24	£21	£18	£15	£12	£9
5	£44	£40	£36	£32	£28	£25	£21	£17	£13
10	£95	£88	£80	£72	£64	£57	£49	£41	£34
15	£147	£135	£124	£112	£100	£89	£77	£66	£54
20	£198	£183	£167	£152	£136	£121	£106	£90	£75
25	£250	£230	£211	£192	£172	£153	£134	£115	£95
-1	-£18	-£17	-£16	-£16	-£15	-£14	-£13	-£12	-£12
-2	-£28	-£27	-£25	-£24	-£22	-£20	-£19	-£17	-£16
-3	-£38	-£36	-£34	-£31	-£29	-£27	-£25	-£22	-£20
-4	-£49	-£46	-£43	-£39	-£36	-£33	-£30	-£27	-£24
-5	-£59	-£55	-£51	-£47	-£44	-£40	-£36	-£32	-£28
-10	-£110	-£103	-£95	-£87	-£80	-£72	-£64	-£56	-£49
-15	-£162	-£150	-£139	-£127	-£116	-£104	-£92	-£81	-£69
-20	-£213	-£198	-£182	-£167	-£152	-£136	-£121	-£105	-£90
-25	-£265	-£245	-£226	-£207	-£188	-£168	-£149	-£130	-£110

Value of Net Impact of Changes in Organ Donation Numbers Using Different Assumptions For QALYs and Assuming 30% of Benefits Accrue to Citizens of Wales

Scenarios for Change in Donor Numbers p.a.	Scenarios for QALY Value								
	£60,000	£55,000	£50,000	£45,000	£40,000	£35,000	£30,000	£25,000	£20,000
	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils	£ Mils
0	-£8	-£8	-£8	-£8	-£8	-£8	-£8	-£8	-£8
1	-£4	-£5	-£5	-£5	-£5	-£6	-£6	-£6	-£6
2	-£1	-£2	-£2	-£3	-£3	-£4	-£4	-£5	-£5
3	£2	£1	£0	-£0	-£1	-£2	-£2	-£3	-£4
4	£5	£4	£3	£2	£1	£0	-£1	-£2	-£3
5	£8	£7	£6	£4	£3	£2	£1	-£0	-£1
10	£23	£21	£19	£16	£14	£12	£9	£7	£5
15	£39	£35	£32	£28	£25	£21	£18	£14	£11
20	£54	£50	£45	£40	£36	£31	£26	£22	£17
25	£70	£64	£58	£52	£46	£41	£35	£29	£23
-1	-£11	-£10	-£10	-£10	-£10	-£9	-£9	-£9	-£9
-2	-£14	-£13	-£13	-£12	-£12	-£11	-£11	-£11	-£10
-3	-£17	-£16	-£15	-£15	-£14	-£13	-£13	-£12	-£11
-4	-£20	-£19	-£18	-£17	-£16	-£15	-£14	-£13	-£13
-5	-£23	-£22	-£21	-£20	-£18	-£17	-£16	-£15	-£14
-10	-£38	-£36	-£34	-£31	-£29	-£27	-£25	-£22	-£20
-15	-£54	-£50	-£47	-£43	-£40	-£37	-£33	-£30	-£26
-20	-£69	-£65	-£60	-£55	-£51	-£46	-£42	-£37	-£32
-25	-£85	-£79	-£73	-£67	-£62	-£56	-£50	-£44	-£38

RIA Appendix 5

Post Implementation Review

The Welsh Government is committed to monitoring and evaluating the effect of the introduction of this legislation. Research to establish baselines commenced in 2012-13. This will be followed with an independent evaluation beginning in 2013-14 that will:

- Monitor statistics such as donor numbers and family consent rates and compare with other parts of the UK.
- Use representative surveys to track public attitudes to the policy, awareness of public communications and intent to opt in or opt out.
- Undertake qualitative research with NHS staff involved with donation before and after implementation of the legislation.

We envisage that this evaluation will publish reports to an agreed timetable as appropriate throughout the life of the work with the final report being available by March 2017.

The Welsh Government will carry out a full review of the impact of the legislation based on this evaluation within five years of implementation. The Minister for Health and Social Services provided the Health and Social Care Committee with a detailed evaluation programme during Stage 2 consideration of the Bill.

Equality Impact Assessment: Organ and Tissue Donation Legislation in Wales

Introduction

142. The Welsh Government is committed to improving the rates of donation in Wales. The shortage of human organs continues to cause unnecessary deaths and suffering, both to patients waiting for a transplant and their relatives. Around 300 people at any one time are on the active waiting list for a transplant and 41 Welsh residents died in Wales in 2011/12 while waiting for an organ donation.

143. This report takes a look at the impact of the proposed legislation on equality in several areas. Evidence was predominantly extracted from the consultation on the White Paper "Proposals for legislation on Organ and Tissue donation", and the subsequent consultation on the draft Bill[48]. Additional evidence was sourced to back up concerns raised by the respondents where necessary.

144. The scope of this report focuses only on how the proposed Bill will impact on how people consent to organ and tissue donation. Issues related to the recipients of the organs or tissues will not be discussed in this report unless relevant.

145. Several organisations provided information contributing to this assessment, including: The Kidney Wales Foundation, Disability Wales, British Heart Foundation and BMA Wales.

146. The Equality Impact Assessment shows that there is a potential differential impact brought about by the soft opt out system, unless all parts of society are aware of the changes and understand how these changes affect them, in order to ensure there is equality in the opportunity to opt in or opt out of organ donation.

147. The consultation responses suggested that issues of pregnancy and maternity, gender or transgender are not affected by the Bill.

148. The Welsh Government is committed to ensuring that everybody has the option to record their wishes for or against donation. This

[48] See footnotes 18 and 19

will improve the rate of donation and will further reassure families that they know the deceased's wishes at a traumatic time.

Disability

149. The Welsh Government wishes to ensure that disabled people are treated on the basis of equality in introducing the new law, and that any different treatment is justified.

150. There are two areas where there are risks arising from different treatment – the approach taken to people that lack mental capacity and the access of all sections of society to information about the new law.

Mental capacity

151. Paragraph 38 of this Explanatory Memorandum sets out that every effort should be made to facilitate those lacking capacity to understand the new arrangements and to make a decision in the light of it.

152. The communications strategy for raising awareness of the legislation will seek to encourage as many people as possible, including those with learning disabilities or mental health problems, to record their wishes for or against donation and ensure their next of kin know those wishes.

153. Where there is no record of an express wish, consent for organ donation will generally be deemed to have been given. It is therefore central to a soft opt-out system that those subject to it are made aware of the legislation, understand it and have the opportunity to opt out. Therefore in order to safeguard those lacking capacity, the Bill provides that consent will not be deemed if an adult who has died lacked capacity for a sufficiently long period before dying to understand that consent is deemed in the absence of express consent.

154. A discussion with the person's family in which these issues are sensitively addressed, backed up with guidance set out in the HTA code of practice, is considered to be the most practical method of determining whether someone has lacked capacity for the requisite period.

Access to information

155. Communication will be vital as a result of the Bill. The Welsh Government will carry out a phased publicity campaign over the two years before the new law comes in to force to educate people living in Wales about the changes. The communications strategy will aim to be as inclusive as possible ensuring that both language and channels are accessible and that barriers to accessing information are removed. The following groups will be targeted specifically as part of the communication strategy:

Deaf people who use British Sign Language

Deaf and hard of hearing people that prefer English or Welsh

People who are blind or have visual impairments

People who are deaf-blind

People who have learning disabilities.

156. Consideration in terms of choice of format will also need to take into account the age of the user and personal preferences of the user.

157. Research of the audience and discussions with disability organisations, contact with networks of disabled people, as well as advice from the Office of Disability Issues will help to ensure that the right methods are used to reach the widest audience as well as ensuring the material developed is as accessible as possible. Resources will be provided for those that support people with learning disabilities to enable them to understand the new law and if they wish opt in or opt out of organ donation.

<u>Action</u>

Ensure the HTA codes of practice are amended to support the Bill includes guidance around mental capacity.

Ensure the communications campaign provides accessible versions of all material and resources to assist those that support people with learning disabilities and other communication issues.

Liaise with stakeholders to trial these materials with representative focus groups before distribution.

Race

158. NHSBT report that currently, people from Black and Minority Ethnic (BME) communities are under represented on the ODR with only 1.4 % being of Asian origin and 0.4 % Black, and yet they are three times more likely to need a transplant. This is because they are more likely to develop conditions such as diabetes and high blood pressure which can lead to kidney failure or heart disease. Finding a match can take longer, meaning that people from these communities on average wait a third longer than others for a transplant. There is also a much better success rate when transplants are carried out within the same ethnic group.[49]

159. Studies[50] consistently demonstrate that while African-Caribbean and South Asian people are supportive of organ donation and transplantation, they are not aware of the specific needs of their community for organs. The earlier consultation[51] responses suggest there is belief BME groups will benefit from the increased numbers of donors.

160. The BME population currently stands at around 4% of the population, which equates to approximately 124,000 people[52]. Their first language may not be English and they may not be able to read English. As with disability groups, information in different languages and which is sensitive to the respective cultures should be made available.

161. For many BME people their faith will be significant in determining their decision on organ donation and this aspect is considered in the Religion, Beliefs and Non-Belief section below.

Action

To work with the respective communities to develop culturally sensitive information in various languages to ensure no minority group is excluded.

Use existing networks and trusted agencies for this work.

[49] http://www.organdonation.nhs.uk/ukt/newsroom/news_releases/article.asp?releaseId=304 .

[50] References shown in Randahawa G. (2011), Achieving equality in organ donation and transplantation in the UK: challenges and solutions. Available from : http://www.better-health.org.uk/briefings/achieving-equality-organ-donation-and-transplantation-uk-challenges-and-solutions .

[51] See footnote 18.

[52] Population estimates by ethnic group 2009, Office for National Statistics

Trial these materials with representative focus groups before distribution.

Follow the communication strategy to maximise the awareness of the changes in minority groups where English is not the first or natural language.

Religion, Beliefs and Non-Belief

162. No religious faiths object completely to the principle of organ donation, although there is a divergence of opinion within Islam. However, religious views are often cited as a reason by relatives not to consent to organ donation. What is less well understood is whether the families have an informed view of their faith's position regarding organ donation based upon extensive debate and thought with their faith mentor, or whether they are expressing an intuitive view based upon their personal interpretation. Both positions are legitimate. However, they do highlight the need to ensure that faith leaders and the public alike should be encouraged to discuss and debate organ donation within the context of their faith.[53]

163. NHSBT has published a range of leaflets outlining the position of each major religion in the UK on organ donation.[54] The consultation on the draft Bill elicited a very large number of responses (over 2,300) from members of the Muslim Communities of Cardiff, Swansea and Newport. The standard letters signed by members of the Communities raised a number of issues, notably the concerns of Muslim people about whether brain death is actual death, and whether donation following brain death (DBD or "heart-beating donation") could in fact be supported within Islamic beliefs. Although this is issue is not directly connected to the proposals for deemed consent, as part of the acknowledgement process, Welsh Government officials sent each respondent a copy of the leaflet produced by NHSBT on the position of Islam with regards organ donation. Further specific work will be needed to ensure members of the Muslim Communities receive all the information they need about the new proposals.

164. The opt-out system allows people, including those with strong religious beliefs, to express their wishes clearly by opting in or opting out. There is also the option of nominating a person to take the decision on consent, which may allow those whose faith has

[53] See footnote 50.

[54] http://www.organdonation.nhs.uk/ukt/how_to_become_a_donor/religious_perspectives/religious_perspectives.asp.

specific requirements at the time of death to ensure those requirements are met while also allowing donation of organs to take place. It is not intended that the new system will alter arrangements for the allocation and matching of organs and tissues. If the individual opts out there is nothing to prevent that individual from being a recipient for a donation and will not alter priorities on the waiting list as all decisions are based on the closest possible match[55].

Action

Ensure that public communications conveys:

- Individuals have a right to express their religious beliefs on organ donation by opting in, opting out, appointing a representative, or indeed by doing nothing in the knowledge that consent will be deemed.
- There is no mandatory requirement to register views one way or another.

Work with a range of faith communities in Wales to ensure there is wide discussion of the issues for different faiths regarding organ donation, to spread awareness of the practices surrounding organ donation, and to explain the new legislation.

Sexual Orientation

165. There is no impact on sexual orientation as a result of this Bill.

Age

166. The consultation responses suggest the Bill will potentially affect two demographics, the elderly and the young.

167. Currently there is no upper limit in age to making an organ donation; if the organs are healthy and a suitable match is found then they could be used for donation. The main issue for older people is that there may be a higher risk group with regards to mental capacity issues. This is discussed in the disability section above.

168. Respondents to the consultation were concerned about potential over-reliance on on-line registration which could disadvantage certain sectors of the community. In particular, the elderly population may not have access to the internet. The Digital Wales:

55 http://www.organdonation.nhs.uk/ukt/about_transplants/organ_allocation/organ_allocation.asp

delivery plan report[56] states that in 2010 approximately 49 per cent of older people (50 and over) are digitally excluded, and as a result may miss out on recording their wishes if the internet became the only way to so. Therefore elderly people and others should be offered a range of ways in which they can record their wishes.

169. The deemed consent system applies to people over the age of 18 and will not apply to children and young people. However, the Bill does not alter the ability of a person under the age of 18 (referred to here as children or young people) to express, during their lifetime, a wish to be a donor or not to be a donor. The proposals will allow children and young people to use the new register arrangements to record their wish.

170. In practice, if a child or young person dies in circumstances where donation becomes a possibility, then their wish to consent to, or not consent to, organ donation will be made known to their family as part of the discussion on organ donation. It would be normal practice for a person with parental responsibility to be consulted to establish whether the child was "Gillick" competent to make the decision. This means the child should have had sufficient maturity to have been able to understand the nature and consequences of their decision. Where a child or young person has not expressed a wish to donate or not to donate, then their consent will not be deemed to have been given and the person with parental responsibility or in a qualifying relationship will be asked to make the decision about organ donation.

171. Young people living in Wales who are approaching their 18th birthday will be identified through NHS systems and contacted six months beforehand. They will be told about the arrangements that will apply to them from the age of 18 – i.e. that unless they have expressed a wish not to be an organ donor, their consent will be deemed to have been given. They will be given enough time to decide whether or not they want to opt out. Young people who have already expressed a wish to be a donor or not to be a donor will be reminded of their decision and advised they need take no further action, unless they wish to change their mind.

172. The Welsh Ministers have considered the impact for the proposals in taking forward the UN Convention on the Rights of the Child. The proposals either respect or give greater effect to those Articles of the Convention that are relevant. A statement of how the Ministers have had due regard will be provided on request.

Action

[56] http://wales.gov.uk/docs/det/publications/110427deliveryplan.pdf .

Ensure elderly people are aware they can donate and that there is no upper age limit to donation.

Work with appropriate focus groups to ensure that information is available for elderly people and that they are aware of the various ways in which they can opt-out e.g. paper based forms, telephone, etc.

Work with young people to develop the best way to inform young people of the decisions they may need to make when they reach the age of 18.

Marriage and Civil Partnerships

173. There is no impact on Marriage or Civil Partnerships. The Bill sets out specifically those that are in a qualifying relationship to the deceased – namely spouse, civil partner, partner, parent, child, brother, sister, grandparent, grandchild, child of a brother or sister, stepfather, stepmother, half brother, half sister and friend of longstanding.

Action

Explain to the public the framework regarding those closest to the deceased and their role in making decisions on organ donation.

Human Rights

174. The Bill will not be in breach of the European Convention on Human Rights (ECHR).

175. The legislation contains safeguards in relation to deemed consent. Deemed consent will not apply to under 18s, people who have not lived in Wales for at least 12 months before they die and people who lack capacity to understand that consent could be deemed in the absence of express action being taken.

176. Further, the legislation provides for relatives or friends of long standing to be able to object based on the known wishes of the deceased.

177. In addition, in practice, people who cannot be identified and/or whose next of kin cannot be contacted will not be subject to deemed consent, since it will not be possible to satisfy the residency and other requirements in those cases.

178. There will be a period of at least two years between the passage of the legislation and its full implementation in which period an extensive communications campaign will be undertaken.

RIA Appendix 7

Privacy Impact Assessment: Collecting Personal Information for new Organ and Tissue Register in Wales

Introduction

179. The aim of this Privacy Impact Assessment is to address concerns regarding the handling of personal data and to identify any risks or issues at an early stage which could affect the running of the proposed new register arrangements.

The Proposal

180. In accordance with the Human Tissue Act 2004 and associated code of practice, organ donation may only proceed with "appropriate consent". This currently means either:

the donor having given express consent while they were alive, for example, by joining the ODR, or

a nominated representative giving express consent after the person's death, or

where the donor had given no instructions for or against, their next of kin being asked to give express consent on their behalf, based on what they think or know the deceased would have wanted.

181. The current legislation does not refer directly to the current Organ Donor Register (ODR). The ODR is a mechanism to record consent while the person concerned is still alive.

182. The Welsh Government's broad proposal is that if the deceased person has not made their wishes known then consent will be deemed to have been given for organ and tissue donation. A new register will be put in place, including options for individuals to consent fully or partially to organ and tissue donation, or to partially or fully opt out of donation. There will be no mandatory requirement to register, however if an individual doesn't choose the opportunity to opt out, subject to caveats in the legislation, it will be deemed that consent has been given.

183. For the proposal to be a success the ICT systems need to be secure and robust to ensure public confidence.

Outline of the proposed system

184. A high level set of requirements have been produced by liaising with key stakeholders. The detailed requirements will be undertaken in partnership with the agreed supplier for the system at a later date.

185. The principal requirements of the new system are follows.

The system will be operated by NHS Blood and Transplant (NHSBT) who operate the existing ODR.

People should be able to register their consent (opt in) to donate some or all of their organs in all the ways they can do at present:

- NHSBT organ donor website
- NHSBT registration phone line
- NHSBT leaflets
- Partner feeds:
  - Driver and vehicle licensing
  - GP registration forms
  - Boots Advantage registration form
  - Via Facebook

Consideration is being given to how to treat any records on the existing ODR of Welsh residents who have registered to be a donor.

The person should be able to record that they do not wish to donate any of their organs or tissues (opt out):

- by phone
- on the web
- by completing a form and returning by mail
- on revised Wales GP registration form

All of these approaches should treat the English and Welsh languages with equal status.

These methods should be accessible to all and the provision of alternative formats should be considered, e.g. Braille, British Sign Language and Easy Read versions.

Records of wishes in relation to donation may be captured from people of all ages and without any consideration of their mental capacity. The Explanatory Memorandum details the processes to be followed for those aged under 18 or those lacking capacity.

When a person registers wishes, a confirmation needs to be issued to the person to confirm that their wishes have been recorded, with the system able to record any corrections that are then notified.

If a referral is made to a Specialist Nurse for Organ Donation[57] because a patient is close to death and may be a potential organ donor, he/she should check these records to establish whether the patient opted in or opted out, or whether there is no record of an expressed view. They should check whether the patient is aged 18 or over and whether they live in Wales, based on a check of their address. This check may be carried out by telephoning a duty officer at NHSBT who consults records on the nurse's behalf. These checks then guide the engagement with the family as set out in the Explanatory Memorandum.

The system must ensure that people are not able to record contradictory wishes, such as both opting in and opting out. The system should accommodate people altering the record of their wishes at different times, and the latest record should be regarded as the person's wishes.

The system should be automatically checked when a potential organ donor is identified anywhere in the UK, in order to identify whether the deceased is a Welsh resident and if so whether they have registered a wish.

If a person moves from Wales to live elsewhere in the UK, any record of their wishes should remain accessible and valid.

Systems should use NHS Wales records in order to contact young people approaching their 18th birthday in order to alert them to the way the law applies when they are 18 and prompt them to make a decision regarding their wishes if they have not already done so.

Consideration should be given to systems which inform people who move to Wales about the Welsh organ and tissue donation system. One way of doing this would be through GP registration.

186. It is expected the register will collect the following details about the individual as identifiers, probably during a validation stage of the process:

Unique ID number (mandatory)
NHS Number (optional)
Driving Licence Number (optional)

Personal Details held will include:

Full name (mandatory)
Address (mandatory)

[57] Specialist Nurses for Organ Donation are employed by NHSBT to facilitate retrievals and transplantation, including acting as the link with bereaved families.

Postcode (mandatory)
Gender (mandatory)
Date of birth (mandatory)
Donation preferences (mandatory)

Additional data that may be recorded include:

Email address
Telephone number
Mobile telephone number
Ethnic classification
Source of registration
Marketing campaign ID
Consent flag for data protection
Data regarding appointed representative(s)

187. There will be a need to incorporate existing feeds that keep the addresses up to date. These feeds however do not offer a guarantee that address information will be completely accurate.

188. The details above are not the final list and may be revised as the project moves forwards.

189. The information held will only be used for the following:

To establish what the person's wishes are in relation to their organs;
To monitor the effectiveness of any marketing campaign; or
To monitor take up of the registration system among minority ethnic groups.

190. Information will be added to the system via the following sources:

Telephone registration via the call centre;
Paper based forms that are added to the system by NHSBT staff or their sub contractors;
Online forms via the internet to register wishes, however individuals will not be able to review or edit their record online;
Feeds from GP registration;
Driving licence applications via DVLA; or
Boots Advantage card.

191. The above list is not final and may be revised.

192. Only the following will have access to the register after they have received the appropriate training:

ODR call centre staff for the purposes of adding information given by an individual over the phone, or to confirm details held;

Sub contractors of NHSBT who handle the paper based forms and undertake data entry for the system;
Duty Officers of NHSBT who access the system on behalf of Specialist Nurses for Organ Donation; and
Specialist Nurses for Organ Donation at the appropriate time during end of life care if they wish to access the system directly rather than obtaining information by telephoning the Duty Officer.

193. It is expected that, due to the personal information available on the register, basic security vetting will apply. It is envisaged that NHSBT will be responsible for the security arrangements regarding their staff that have access to the register.

194. All data will be encrypted and backed up by NHSBT.

Justification

195. The earlier sections of this Explanatory Memorandum set out the justification for the policy that necessitates new systems.

Safeguards

196. The Review of the Organ Donor Register[58] by Professor Sir Gordon Duff highlights the needs for a robust system to ensure that the public have faith in the system. The report set out nine recommendations for the existing ODR. These recommendations, which are being implemented by NHSBT, should be considered in the development of the new system, as and where appropriate.

197. The key recommendations from the Duff report that should be considered are as follows:

Recommendations 2, 3 and 4 aim to reduce the risk of errors arising and ensure as far as possible the system is accurate.

Recommendation 7 suggests when individuals register their wishes, they are provided with additional information either via the internet or printed materials. This can help ensure that individuals have made an informed choice.

Recommendation 8 is an important one as it suggests that individuals are encouraged to inform their families of their wishes, as the family are likely to be asked to confirm their wishes.

Recommendation 9 encourages clarity to ensure there is no misunderstanding as required by the 2004 Act.

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http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120563

198. A Data Protection Policy will be developed to ensure there are appropriate security controls for handling personal data and that there is clear accountability for maintaining the appropriate security levels.

Legislation

199. The following legislation will need consideration

The Human Rights Act 1998

Data Protection Act 1998

The Regulation of Investigatory Powers Act 2000

Lawful Business Practice Regulations 2000

The Privacy and Electronic Communication Regulations 2003

The Data Retention (EC Directive) Regulation 2007

200. Data Protection Act compliance will require that a copy of an individual's record should be made available on request and amended if inaccurate.

Risks/Issues

201. The most significant risk for the proposed legislation is the risk of error that an individual has wished to object to organ donation and their consent was mistakenly treated as given.

202. The system will need to ensure the new system is as robust and secure as is practicable. In building new register arrangements, the recommendations of the Duff review should be adopted and full analysis of security weaknesses undertaken.

Annex 1

Explanatory Notes

Introduction

1. These Explanatory Notes relate to the Human Transplantation (Wales) Bill. They have been prepared by the Department for Health and Social Services of the Welsh Government in order to assist the reader in their understanding of the Bill. They do not form part of the Bill.

2. The Explanatory Notes need to be read in conjunction with the Bill and are not meant to be a comprehensive description of the Bill.

Background and summary

3. The current law on consent for the use of bodies and relevant materials is set out in the Human Tissue Act 2004. The 2004 Act authorises certain activities, including the removal and use of organs and tissues, for a number of purposes that are set out in Schedule 1 to that Act. One of these is use for the purpose of transplantation. The current position, as set out in the 2004 Act, is that "appropriate consent" is required for the use of organs and tissues for the purposes listed in the Schedule. The meaning of appropriate consent differs depending on whether the relevant material is obtained from an adult or child, but the overarching principle is that the consent must be given expressly.

4. The purpose of the Bill is to change the way in which consent is to be given to organ and tissue donation in Wales, for the purposes of transplantation. The Bill provides that, in the absence of express provision in relation to consent, consent will be deemed to have been given in most cases. This means that, after death, a person's consent will be deemed to have been given unless they had expressed a wish for or against donation. However, deemed consent does not apply to the under 18s, people who have not lived in Wales for at least 12 months before they died, and people who lack capacity to understand that consent could be deemed in the absence of express action being taken. In addition, in practice people who cannot be identified or whose next of kin cannot be found will not be subject to deemed consent.

5. The Bill therefore creates a default position which provides that consent is given and it is up to individuals to opt out if they object. However, deemed consent can be overturned where a relative or friend of long standing objects on the basis they knew that the deceased would not have consented to their organs and tissues being donated for the purpose of transplantation. This is what is often referred to as a "soft opt-out system" for organ and tissue donation. The notion of "appropriate consent" from the 2004 Act is therefore replaced by two concepts,

"express consent", (which replicates "appropriate consent") and "deemed consent".

6. For those people to whom deemed consent will not apply, the Bill captures the meaning of the concept of appropriate consent as set out in the Human Tissue Act 2004. This means the status quo will remain for a person who dies in Wales but who is not subject to deemed consent. In summary, therefore, with the exception of deemed consent applying in Wales, the systems in England and Wales remain the same.

Territorial application

7. The Welsh legislation applies in relation to consent where a transplantation activity takes place in Wales. The Human Tissue Act 2004 applies in all cases relating to consent for the purposes of transplantation where the activity takes place in England or Northern Ireland.

8. The Bill sets out in one place the main provisions relating to consent for transplantation activities in Wales. As a result, the Bill restates certain sections of the 2004 Act directly related to consent for the purposes of transplantation. However, in order to maintain an effective cross-border regime in terms of the operation of the UK-wide organ transplantation programme, there is an inevitable interplay with the 2004 Act. Certain other provisions of the 2004 Act not directly related to consent but applicable to transplantation, have not been restated but continue to apply in Wales. These include provisions relating to the Human Tissue Authority and sections 8 (restriction of activities in relation to donated material), 33 (restriction on transplants involving a live donor) and 34 (information about transplant operations) of the 2004 Act.

Commentary on sections

Section 1 - Overview

9. This section summarises the main provisions of the Bill. It is intended to be a sign posting provision and to introduce key concepts.

Section 2: Duty of the Welsh Ministers to promote transplantation

10. Although partly general in its application (promoting transplantation as a means of improving health), this provision also contains an important specific duty on Welsh Ministers relating to educating those resident in Wales (and potentially those likely to become resident) about the circumstances in which consent can be deemed. This is important because inaction amounts, in effect, to consent. This provision is not expressly confined to Wales (as a geographical concept) due to there being a need for flexibility in relation to where promotional and educational activity takes place.

Section 3: Authorisation of transplantation activities

11. This is the key provision which provides that consent is required in order to carry out a transplantation activity. It introduces the concepts of deemed and express consent. It also sets out the transplantation activities to which the consent applies. It follows a similar structure to the Human Tissue Act 2004 in that it provides that certain activities are lawful if done with consent, with the means by which consent is given in various circumstances following in subsequent sections.

12. This section provides that certain activities undertaken for the purpose of transplantation are lawful if done with consent, either express or deemed, and signposts the relevant sections which provide for what this means in different circumstances. The subsequent sections set out what is meant by express and deemed consent depending on whether the person to whom the consent relates is an adult, an excepted adult (an adult to whom deemed consent cannot apply) or a child.

13. The activities themselves are again based on those contained in section 1 of the 2004 Act, except that only those relevant to transplantation are included.

14. Subsection (3) makes certain activities lawful where organs and tissues have been imported into Wales from outside Wales. In such cases consent is not required, meaning that all that a person using organs need be satisfied about is that the organ has been imported. This replicates the position under the 2004 Act where an organ has come into England, Wales or Northern Ireland from outside (for example from Scotland).

Section 4: Consent: adults

15. This section introduces the concept of deemed consent. Deemed consent is the default position in all cases apart from excepted adults (see section 5). Children are also exempt from the deemed consent regime (see section 6).

16. For those people to whom deemed consent can apply, there are further possible exceptions – these are:

Exception 1:

17. Where a case set out in the first column of Table 1 applies, in which case the consent must be provided expressly. These cases are:

    a) where the adult is alive; in such a case it is the adult who must give consent (meaning that deemed consent can never apply when an adult is alive – though there is an exception to this in section 8 in cases where a person lacks capacity);

b) where the adult has died but a decision of his or hers about consent for transplantation was in force immediately before death – in such cases that decision prevails;

c) where the adult has died, no decision of his or hers is in force, but the adult has appointed another person to take the decision (under section 7 of the Bill) – in that case the person appointed decides;

d) where the adult has died and appointed another person to take the decision (under section 7 of the Bill) but no-one is able to give consent under the appointment – in that case the decision on consent falls to qualifying relatives in ranked order, as in the 2004 Act.

18. The factual concepts behind consent are the same in the Welsh Bill and the Human Tissue Act 2004 and reflect an intentional interplay between the two pieces of legislation. For example, the factual question of whether there is "a decision of a person to consent, or not to consent, to a [transplantation] activity …. in force immediately before his or her death" is the same whether the legal framework is the Welsh legislation or the 2004 Act. In this way, the two pieces of legislation are intended to sit side by side each other.

19. If a person is alive and normally lives, for example, in England and takes part in a transplantation activity in Wales, as a matter of law the Welsh Bill applies. However the effect is the same as if the 2004 Act applied (i.e. that person's consent is required).

20. If a person who would normally fall within the provision of this section dies in England, his or her consent cannot be deemed to have been given to a transplantation activity that takes place in England. The 2004 Act would apply and therefore a person in a qualifying relationship would decide in the absence of express consent. This result is achieved in two ways. The first is that the 2004 Act continues to apply where a transplantation activity takes place in England (or Northern Ireland) and under that Act the question of fact relating to whether a decision of the deceased relating to consent (in practice being on the Organ Donor Register) was in force when he or she died is the same.

21. Appointments of representatives nominated to take the decision relating to consent after death made under either the 2004 Act or the Welsh legislation are recognised in a cross border situation. This is done by a provision in both pieces of legislation (section 7(11) of this Bill and new section 4(11) of the 2004 Act, to be inserted by an order made by the Secretary of State pursuant to section 150 of the Government of Wales Act 2006) by which appointments made under one Act can be treated as having been made under the other.

Exception 2:

22. A relative or friend objects on the basis that they knew the deceased wished to object to donation. Such an objection to consent being deemed can be made by any relative or friend of long standing of the deceased. The person making an objection does not have to be a qualifying relative as defined in Section 17 of the Bill. However, any objection must be based on the known views of the deceased and not on the views of the relative or friend.

23. An objection must therefore-

    (a) be provided by a relative or friend of long standing who knew the views of the deceased in relation to consent for transplantation activities, and

    (b) be based on information provided about the deceased's wishes that indicates that the deceased would not have consented to transplantation activities. It should lead a reasonable person to conclude that the person objecting did indeed know the most recent views of the deceased.

Exception 3:

24. The transplantation activity involves relevant material of a type specified by the Welsh Ministers in regulations.

Section 5: Consent: excepted adults

25. This section provides for the meaning of consent in relation to a transplantation activity for excepted adults. In the case of an excepted adult, express consent will always be required and deemed consent does not apply. This section replicates the existing legal position under the Human Tissue Act 2004 so as to require either the express consent of the individual, or the express consent of a qualifying relative or the express consent of an appointed representative. It applies to deceased donation only, and not living donation. This is because consent can only be deemed where a person has died (unless section 8 on living persons who lack capacity applies).

26. A qualifying relationship is defined in the interpretation section (see section 17). The ranking of the list of qualifying relations is as set out in section 27(4) of the 2004 Act.

27. An excepted adult means:

A deceased adult who has not been ordinarily resident in Wales for a period of least 12 months immediately before death; or
A deceased adult who lacked capacity for a significant period before death to understand that consent is deemed in the absence of express consent

28. The term "ordinarily resident" is not defined, but it has been the subject of extensive case law. Ordinarily resident is primarily a question of degree and fact and connotes some habit of life and is to be contrasted with extraordinary, occasional or temporary residence. The concept means a person's abode in a particular place or country which has been adopted voluntarily and for settled purpose and part of the regular order of life for the time being, whether or short or long duration. A settled purpose could include education, business, employment, health or family. All that is necessary is that the purpose of living in a place has a sufficient degree of continuity to be properly described as settled, and apart from accidental or temporary absences.

29. In terms of a person who lacked capacity to understand that consent could be deemed, the exact duration that a person must have lacked capacity has not been specified. The period must, however, be significant. If a person had capacity for a prolonged period not long before they died then consent should be deemed. It is important to note that the capacity issue here (lacking capacity to understand that consent can be deemed) is slightly different to the capacity issue in section 8 (and in section 6 of the 2004 Act).

30. Under this section if no express provision (the cases in Table 2, including appointed representatives) is made, then the decision regarding consent is taken by a qualifying relative. This is the same as the position under the 2004 Act. Qualifying relatives are defined in this Bill but the ranking given to them (i.e. which relative takes the decision) is (still) done under the 2004 Act. Under section 26 of the 2004 Act the Human Tissue Authority must issue a code of practice for the purpose of "giving practical guidance" and "laying down the standards expected" in carrying on activities with bodies and organs (including transplantation). Section 26(3) of the 2004 Act includes a specific provision to say that the Code must deal with the issue of consent. Section 27 goes on to provide that the code must "include provision to the effect" set out in subsections (4) to (8), which includes ranking and other related practical matters, though the Authority may by virtue of subsection (3) include provision of different effect in "exceptional cases". These 2004 Act provisions will continue to apply in Wales in respect of express consent given by qualifying relatives, but the code of practice will make clear that relatives and friends of long standing will not be ranked for the purposes of information provided under section 4(4)(b) of the Bill.

31. As to the cross border effect, this section is intended to work such that if somebody who ordinarily lives in England dies in Wales, and therefore the transplantation activity is done in Wales, the legal position is the

same. This position is achieved as the question of fact relating to whether a decision of the deceased relating to consent (in practice being on the Organ Donor Register) was in force when he or she died is the same.

Section 6: Consent: children

32. Section 6 sets out the arrangements that apply to children and young people who die in Wales. These restate the provisions in section 2 of the Human Tissue Act 2004. For children and young people, either their own express consent or if that has not been given, the consent of a person with parental responsibility will apply. Where no such person exists then the consent of a person standing in a ranked qualifying relationship to them, as provided for in section 27(4) of the 2004 Act, must be given.

Section 7: Appointed representatives

33. This section provides that an adult may appoint a representative(s) to give consent to any of the activities set out in section 3. This section replicates section 4 of the Human Tissue Act 2004 but with two differences, one of which is that a new provision has been added so that the Welsh legislation recognises an appointment made under the 2004 Act. The second is that it is the Welsh Ministers who will hold the power to prescribe in regulations that persons of a particular description cannot act under an appointment in relation to somebody who dies in Wales (the equivalent power in the 2004 Act held by the Secretary of State has never been used).

34. An appointment made under this Bill will be recognised by the 2004 Act (once relevant amendments have been made to that Act by the Secretary of State pursuant to section 150 of the Government of Wales Act 2006) and similarly an appointment made under the 2004 Act is recognised by this Bill. It does not therefore matter whether the activity would take place in England, Wales or Northern Ireland.

35. Section 7(12) specifies that if it is not reasonably practicable to communicate with an appointed representative, in time for consent to be acted on, then the appointed representative is treated as not able to give consent. This would mean that the decision on consent would pass to qualifying relatives if no appointed representative can be contacted in time.

Section 8: Activities involving material from (living) adults who lack capacity to consent

36. This section applies where a living adult lacks capacity to consent to donation and no decision is in force. This section has the same effect as section 6 of the Human Tissue Act 2004, except that the power to prescribe in regulations when deemed consent can apply will be held by

the Welsh Ministers as regards a transplantation activity in Wales. This power could be used to prescribe that consent could only be deemed if it is in the best interests of the living adult. For example, it could be in the best interests of the person who lacks capacity to donate relevant material to a close relative. Deemed consent in this context is separate from the deemed consent provisions set out in section 4, which relate to deceased donors. However, the basic premise of taking action without the express consent of the individual is the same.

Section 9: Prohibition of activities without consent

37. This section makes it a criminal offence in Wales to undertake the transplantation activities set out in section 3 without consent. A person has a valid excuse, however, if the person concerned reasonably believed that consent was in place. This is the main enforcement provision of the Bill and is based on section 5 of the Human Tissue Act 2004. As the provision is built on a slightly different foundation than the 2004 Act (there being no exact equivalent of "appropriate consent" in the Bill) there is a need to expressly exclude other provisions in the Bill which make transplantation activities lawful without consent. This explains the reference to section 3(3) and section 12(1).

38. Subsection (5) specifies the meaning of the consent that is required. This is a question of fact and includes consent given or obtained before the coming into force of this Bill.

Section 10: Offences by bodies corporate

39. This section is based on a similar provision in section 49 of the Human Tissue Act 2004.

Section 11: Prosecutions

40. This relates to the criminal offences that can be committed under this Bill and replicates the effect of section 50 of the Human Tissue Act 2004.

Section 12: Preservation for transplantation

41. This section replicates the effect of section 43 of the Human Tissue Act 2004. This section makes it lawful to retain the body of a deceased person and preserve organs in the body which may be suitable for transplantation, while the issue of consent (whether express or deemed) to the use of organs is resolved. The actions taken for preservation must involve the minimum steps necessary and the least invasive procedures. Whilst this is not directly related to consent it is inherent to how the system works before it is established whether consent exists and has therefore been restated in this Bill. An amendment has been made to the corresponding section 43 of the 2004 Act to make clear which provision applies (i.e. the one in the Bill).

Section 13: Coroners

42. In order to maintain the current legal position regarding coroners, this section exempts from the requirements of the Bill anything done for the purposes of the functions of a coroner, or under his authority. This section provides that before acting on authority under section 3 or section 12, if a body or relevant material is or may be required for the purposes of the functions of the coroner, the coroner's consent is required. This section replicates the effect of section 11 of the Human Tissue Act 2004.

Section 14: Codes of practice

43. As referred to above the Human Tissue Authority is required to issue a code of practice which includes practical guidance and standards. These provisions have not been replicated or restated in the Bill as there is only one Authority and one Code. Amendments have therefore been made to the Human Tissue Act 2004 to reflect the Welsh legislation. This includes a power for the Welsh Ministers to amend by statutory instrument the ranking of those in a qualifying relationship to the deceased and a requirement for the Code to give guidance on how a relative or friend of the deceased can object to deemed consent on the basis of the deceased's wishes.

44. The amendments to the 2004 Act also provide that the Authority may not issue a code which relates to activities caught by the Welsh legislation unless a draft has been approved by the Welsh Ministers and by the National Assembly for Wales (the latter subject to affirmative resolution).

Section 15: Consequential and incidental amendments to the Human Tissue Act 2004

45. This section makes a number of amendments to the Human Tissue Act 2004 which are consequential or incidental to this Bill. Amendments are made to section 1(1) of the 2004 Act which have the effect of disapplying in relation to a transplantation activity done in Wales the provisions for appropriate consent for transplantation activities in the 2004 Act. This means section 1(1) of the 2004 Act will no longer apply to consent for transplantation activities carried out in Wales.

46. Other amendments disapply sections of the 2004 Act which have been restated for Wales in this Bill (for example, sections 6 (adults who lack capacity), and section 43 (preservation for transplantation)).

47. Amendments are also made so that the general functions of the Human Tissue Authority and its annual report recognise this Bill. Powers of inspection, entry, search and seizure are also amended so as to incorporate situations covered by the Bill.

48. References to the National Assembly for Wales that (by virtue of the effect of Schedule 11 to the Government of Wales Act 2006) actually mean the Welsh Ministers have been textually amended so as to assist the reader. New requirements for the Welsh Ministers to lay documents before the National Assembly for Wales have also been added to reflect the new constitutional arrangement post the Government of Wales Act 2006 (so that they replicate the provisions for the Northern Ireland Assembly and the UK Parliament).

Section 16: Relevant material

49. This section defines what is meant by the material removed from the body for the purpose of transplantation. The definition is the same as that in section 53 of the Human Tissue Act 2004.

Section 17: Interpretation

50. A definition of qualifying relationship is included in addition to the reference to the ranking of those relationships in section 27(4) of the Human Tissue Act 2004. The 2004 Act defines the term (at section 54(9)) as well as giving the different relationships that form the definition a ranking through section 27(4) and the Code of Practice issued by the Human Tissue Authority. Relatives and friends of long standing will not be ranked for the purposes of section 4(4)(b) of this Bill (information that can prevent deemed consent), but qualifying relations will be ranked for all other purposes.

Section 18: Orders and regulations

51. This section provides that the affirmative procedure will be used for making subordinate legislation under this Bill (except for commencement orders). This means that subordinate legislation may not be made unless the Welsh Ministers have carried out a public consultation, and a draft has been laid before and approved by the National Assembly for Wales.

Section 19: Commencement

52. This section deals with the commencement of this Bill once it has received Royal Assent. Section 2, which places a duty on Welsh Ministers to promote and provide information about transplantation, will be commenced on Royal Assent, as will Sections 1 (Overview); 19 (Commencement) and 20 (Short Title). The remaining provisions will be commenced no sooner than two years following Royal Assent.

Section 20: Short title

53. The short title of the Bill is the Human Transplantation (Wales) Act 2013.