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Consultation Document

Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper

Date of issue: **8 November 2011**

Responses by: **31 January 2012**

Overview

This consultation seeks responses on the Welsh Government's proposals for legislation on organ and tissue donation.

The objective of an Assembly Bill relating to organ and tissue donation is to introduce a system in Wales which aims to increase the number of organ and tissue donors in Wales, allowing more lives to be saved and to improve the quality of life of others.

Your responses will be considered in developing the Bill.

How to respond

The consultation responses form is available for completion at www.wales.gov.uk/consultations. Responses are welcome in either English or Welsh.

Responses to this consultation should be sent by e-mail or by post to the address below to arrive no later than 31 January 2012.

Further information and related documents

Large print, Braille and alternative language versions of this document are available on request.

An Easy-Read version of this document has been developed and is available from the address below.

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Data Protection

How the views and information you give us will be used.

Any response you send us will be seen in full by Welsh Government staff dealing with the issues which this consultation is about. It may also be seen by other Welsh Government staff to help them plan future consultations.

The Welsh Government intends to publish a summary of the responses to this document. We may also publish responses in full. Normally, the name and address (or part of the address) of the person or organisation who sent the response are published with the response. This helps to show that the consultation was carried out properly. If you do not want your name or address published, please tell us this in writing when you send your response. We will then blank them out.

Names or addresses we blank out might still get published later, though we do not think this would happen very often. The Freedom of Information Act 2000 and the Environmental Information Regulations 2004 allow the public to ask to see information held by many public bodies, including the Welsh Government. This includes information which has not been published. However, the law also allows us to withhold information in some circumstances. If anyone asks to see information we have withheld, we will have to decide whether to release it or not. If someone has asked for their name and address not to be published, that is an important fact we would take into account. However, there might sometimes be important reasons why we would have to reveal someone's name and address, even though they have asked for them not to be published. We would get in touch with the person and ask their views before we finally decided to reveal the information.

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FOREWORD BY MINISTER FOR HEALTH AND SOCIAL SERVICES

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 51 people died in Wales in 2010/11 while waiting for an organ donation.

We are already implementing all the recommendations of a UK wide review and have made good progress. Last year 83 Welsh residents donated organs – a record number.

However, we are committed to taking things a stage further, as the number of organs available for transplantation is still insufficient to meet the need. The Welsh Government's aim is to increase the number of organs available for transplantation after death, in order to improve the health and quality of life for people who need a transplant. We will do this through implementing our manifesto commitment to bring forward an Assembly Bill to introduce an opt-out system of organ donation.

Our debates and consultations on this issue in recent years have convinced us that Wales is ready to take this step, as a nation known for altruism, generosity and thought for others. Wales has taken the lead on organ and tissue donation in the past, pioneering the concepts of a kidney donor card and a computerised Organ Donor Register. We believe we should continue to be progressive on this issue and follow the example of those European countries with excellent records in organ donation, introducing a soft opt-out system as one element of a package of measures to increase organ and tissue donor numbers. Please respond to this consultation and help us to get it right.

We propose that if you want to record your wishes to donate on the current Organ Donor Register, you will still be able to do so. You can actually do that right now. Details of how to get on the Organ Donor Register are in this White Paper.

Finally, please talk to those close to you about your belief in organ and tissue donation as this will make it much easier for them to understand your wish to donate in the event of your death.

Lesley Griffiths AM
Minister for Health and Social Services

EXECUTIVE SUMMARY

1. This White Paper sets out the Welsh Government's proposals for a soft opt-out system of posthumous organ and tissue donation in Wales.
2. The soft opt-out system that is being proposed for Wales is one in which the removal and use of organs and tissues is permissible unless the deceased objected during his or her lifetime. Individuals will have a formal mechanism for registering that objection. After death relatives will be involved in the decision making process around donation.
3. The Welsh Government is making this change to increase the number of organs available, because on average approximately one person in Wales dies each week as a donor cannot be found to enable transplantation to go ahead. Organ and tissue transplantation is one of the most effective forms of modern medical treatment that saves lives and improves quality of life for patients with organ failure. Transplants are the best possible treatment for most people with organ failure.
4. At the same time, other people die in circumstances where donation of their organs and tissues would be possible but does not happen. This is not because the deceased person objected to donation, but because they had not got round to signing the Organ Donor Register.
5. Evidence from other countries has shown that a system, such as the soft opt-out system being proposed for Wales, can increase the number of organs available for donation and therefore can save lives. Earlier consultations undertaken by the Welsh Government indicate public support for legislative change to a soft opt-out system.
6. This White Paper sets out the detail of the proposed soft opt-out system for Wales that covers the transplantation of organs and tissues from deceased persons. The key features of which are:
 - a) it will apply to people aged 18 or over who live and die in Wales;
 - b) those adults will have the opportunity to make an objection to donation of their organs and tissues;
 - c) there will be an effective and secure system for individuals to make an objection to donation should they wish to, and such a system will enable objection to donation of some or all organs and tissues;
 - d) any objection of an individual to donate organs and/or tissues will be upheld, after death;
 - e) the system will support the opportunity for individuals to change their minds, and to include people who move to Wales or who reach the age of 18;
 - f) after death families will be involved in the decision making process around donation.

7. The proposals will apply to the donation of organs and tissues for the purposes of transplantation only. It will not include the donation of organs and tissues for other purposes, such as research, display or commercial use.
8. There are often concerns that under a soft opt-out system individuals lose rights over their bodies and power to remove organs and tissues for transplantation is in the hands of the state. However, evidence shows that individuals are more likely to make decisions about donation during their lifetime under such a system. Individuals will also have their decision respected after death. Moreover, the burden of making a decision is removed from relatives in the most difficult of circumstances, when they often have no clear indication of what the deceased would have wanted.
9. The earliest that the soft opt-out system will be in operation in Wales is 2015. Prior to the new system coming into effect there will be a major public awareness campaign to ensure that all those people who wish to opt-out know how to do so.
10. The Welsh Government is undertaking a consultation on the proposals set out in this White Paper. Responses to the consultation should be submitted to the Welsh Government by **31 January 2012**, and guidance on how to do this is set out in Annex A.

THE CASE FOR CHANGE

1. In Wales, in 2010/11, 51 people died whilst on the waiting list or following removal from the list due to deterioration in their health. Across the United Kingdom more than 1,000 people die each year while waiting for an organ transplant.
2. At the same time, other people die in circumstances where donation of their organs and tissues would be possible, but does not happen. Not because the deceased objected to donation, but because they never got round to signing the NHS Organ Donor Register (ODR) or informing their relatives of their wishes.
3. Organ and tissue transplantation is one of the most effective forms of modern medical treatment that saves lives and improves quality of life for patients with organ failure. Transplants are the best possible treatment for most people with organ failure.
4. Donation covers organs and tissues including kidneys, heart, liver, lungs, pancreas, the small bowel, corneas and sclera (from the eyes), valves and pericardium (from the heart), skin, bone, tendons and cartilage.
5. While almost all of us would be willing to accept an organ or tissue transplant, only 31 per cent of the population in Wales are currently on the ODR. Research suggests that many more people would like to join the register but have not yet done so. Creating an environment in which donation is the normal choice will enable more organs and tissues to be available when they are needed the most.
6. International comparisons illustrate there are a range of factors which influence organ donation rates and the introduction of an opt-out system is one of those factors. Research suggests that organ donation rates from deceased persons increase by approximately 25 to 30 per cent in countries where an opt-out system applies.
7. The Welsh Government believes that a move to a soft opt-out system for donation will normalise donation, encourage and enable discussion about these issues, and increase the number of organs and tissues available for those in most need.

What is happening now

The legal framework

8. The Human Tissue Act 2004 is the legislative framework for organ and tissue donation in Wales, England and Northern Ireland. Similar provisions apply in Scotland under the Human Tissue (Scotland) Act 2006.
9. Both legal frameworks provide an opt-in system. An opt-in system is based on explicit consent where individuals volunteer to become organ and tissue donors.

Consent does not have to be in writing, but in practice most decisions to donate involve carrying a signed donor card, or actively joining the ODR.

10. Individuals have to take positive steps to record their wishes to donate.

11. However, where a person has not made a known decision for or against donation, the family may still consent to donation on behalf of the deceased. During 2010/11 just over 67 per cent of donors in the UK were not on the ODR.

The NHS Organ Donor Register (ODR)

12. The ODR is a confidential, computerised database which holds details of people who have signed up to become organ and tissue donors in the event of their death. The Register is used after a person has died to establish whether they wanted to donate and if so, which organs and tissues.

13. Members of the public can sign up to the register in a variety of ways, including:

- registering online (www.organdonation.nhs.uk);
- by contacting the NHS Donor Line (0300 123 23 23);
- when registering for a driving licence with the Driver and Vehicle Licensing Authority (DVLA);
- when registering with a GP;
- when requesting a European Health Insurance Card;
- applying for a Boots Advantage Card.

14. Donated organs are allocated for transplantation according to need and the matching of blood and tissue type, on a UK basis. They are matched by blood group and in the case of kidneys, for tissue type. The best matched transplants have the best outcome.

Moving to a soft opt-out system

15. The Welsh Government sought views in 2008/09 on how to increase the number of organ donors. This included a series of public meetings across Wales, including an inter-faith meeting, and took account of written views and a telephone survey.

16. This generated public debate which confirmed significant support for increasing organ donation rates. A wide range of suggestions were put forward on how this might be achieved, including possible changes to the system of consent for donation.

17. The debate confirmed people in Wales were keen for a change to the organ donation consent system, with a number preferring a soft opt-out system.

18. On the back of the public discussion and debate, the Welsh Government published a consultation paper, *Options for changes to the organ donation system in Wales*. The result of consultation showed strong public support for the Welsh Government to pursue legislative change and introduce a soft opt-out system of organ donation in Wales.

19. In the First Minister's legislative statement of 12 July 2011, he set out that the Welsh Government will "...launch a white paper consultation on an *Organ Donation (Wales) Bill* before the end of this year. The Bill will provide for an opt-out system of organ donation, backed by a comprehensive communication programme."

20. This White Paper sets out the Welsh Government's proposals for a soft opt-out system of posthumous organ and tissue donation for the people of Wales.

THE PROPOSED SOFT OPT-OUT SYSTEM FOR WALES

21. Opt-out systems are characterised as hard or soft:
- a) in a hard opt-out system the removal and use of organs and tissues is permissible unless the deceased objected during his or her lifetime;
 - b) in a soft opt-out system the removal and use of organs and tissues is also permissible unless the deceased objected during his or her lifetime, but after death relatives are involved in the decision making process around donation.

The Welsh Government is proposing a soft opt-out system for Wales.

22. The key features of the soft opt-out system of posthumous organ and tissue donation that the Welsh Government intends to introduce for Wales are:

- a) it will apply to people aged 18 or over who live and die in Wales;
- b) people will have the opportunity to make an objection to donation of their organs and tissues;
- c) there will be an effective and secure system for individuals to make an objection to donation should they wish to, and such a system will enable objection to donation of some or all organs and tissues;
- d) any objection of an individual to donate organs and/or tissues will be upheld, after death;
- e) the system will support the opportunity for individuals to change their minds, and to include people who move to Wales or who reach the age of 18;
- f) after death families will be involved in the decision making process around donation.

Persons who will be included in the soft opt-out system

23. The soft opt-out system for Wales will apply to people aged 18 or over who live in Wales, and who have had the opportunity to make an objection to donation of their organs and tissues in the event of their death.

The opportunity to make an objection to donation

24. The Welsh Government believes everyone has the right to object to donate their organs and tissues in the event of their death, and to have that right respected. In order to ensure an objection can be made, the opportunity to object must exist and be given.

25. In order to ensure an individual has the opportunity to make an objection, there must be:

- a) access and availability of information about the soft opt-out donation system in Wales;
- b) an ability on the part of the individual to understand the information available and reach a decision; and
- c) a system by which objection can be made.

26. The Welsh Government's proposals for the process for making and recording the objection are set out later in this White Paper.

Living in Wales

27. The Welsh Government is not proposing that the new legislation will cover all people who die within Wales, only those who both live and die in Wales.

28. Further, the Welsh Government proposes the new arrangements will apply to people who have lived in Wales for a sufficient time in order to gain knowledge and understanding of the system.

29. The reason for applying the arrangements to people who both live in Wales and have lived here for a sufficient period of time is to seek to ensure that such people will be aware of the system and know of the mechanisms to object; it cannot be expected that people who visit Wales will know of the arrangements, and have had the opportunity to object.

30. It is recognised that the legislation will need to provide certainty as to the meaning of living in Wales.

31. Whether a person is considered to be usually living in Wales or not, will need to reflect their usual daily lives, and not be swayed by temporary absences (such as holidays, recreation and business). The mechanism devised will need to be clear to the clinicians and to the public.

32. As set out above, a person must have lived in Wales for a period of time to enable them to have gathered sufficient knowledge and understanding of the soft opt-out system of organ and tissue donation. Views on the period of time are sought as part of this White Paper.

33. There will be an extensive and wide-ranging programme of awareness raising in the lead-up to the introduction of the new system. This will seek to ensure those people living in Wales will be aware of the new arrangements and the choices available to them.

34. When the new arrangements are operational, we will ensure people moving to Wales have sufficient time to gain the knowledge and understanding of the system so they may object to donation if they wish. These safeguards will establish the period of time required prior to being included within the soft opt-out system.

Consent

35. Opt-out systems, such as the soft opt-out system being proposed for Wales, are sometimes referred to as a “*presumed consent*” system of organ and tissue donation.

36. Consent is central to most organ and tissue donation systems. This is because consent is generally seen as the ethical and legal justification for the removal and use of organs and tissues.

37. Under the current opt-in system in place in Wales, consent for donation is given when individuals volunteer to become organ and tissue donors by actively joining the NHS Organ Donor Register (ODR). Additionally, in the absence of consent from the individual, the family may also consent to donation on behalf of the deceased where that person has not made a known decision for or against donation.

38. Under the proposed soft opt-out system for Wales, unless an individual makes an objection their organs and tissues will be available for donation after their death. Therefore consent for donation, in the absence of objection, is presumed. As a safeguard, after death families will be involved in the decision making process around donation.

Ability to understand

39. The Mental Capacity Act 2005 confirms that a person must be assumed to have capacity to make decisions unless it is established otherwise. This principle will not be altered by the proposed soft opt-out system for organ and tissue donation in Wales.

40. We recognise that under the current organ donation arrangements the mental capacity of an individual to understand the nature of the decision to join the Organ Donor Register (ODR) is not tested.

41. People may have the mental capacity to make decisions about some aspects of their life, but not others. It is recognised that some people may never have the mental capacity to make a particular decision, some may lose the mental capacity to make that decision, and for others their mental capacity may fluctuate.

42. The consequence of this is that no organ and tissue donation system which relies on an individual’s opportunity and ability to opt-out can make a simplistic division between those with, and those without, sufficient mental capacity to decide.

43. The Welsh Government proposes that clinicians will, in the event of the death of an adult and in discussion with their family, identify those people who lacked capacity to make a decision about organ and tissue donation.

Adults aged 18 years and over

44. The Welsh Government recognises there are difficulties inherent in assuming children will understand the nature and purpose of donation of their organs and tissues, in order that they may object to such an action.

45. Section 2 of the Human Tissue Act 2004 sets out the current meaning of 'appropriate consent' in relation to activities regarding the body of a deceased child. For the purposes of that section, children are people under the age of 18.

46. We therefore propose children and young people who have not attained the age of 18 years will not be included under the move to a soft opt-out system; the system will incorporate young people when they reach their eighteenth birthday.

Persons that will not be covered by the new arrangements

47. The following will not be included within the soft opt-out system of organ and tissue donation for Wales:

- a) persons who die in Wales but who do not normally live in Wales (for example visitors);
- b) persons who die in Wales and normally live in Wales, but have not lived in Wales for the required length of time;
- c) persons who usually live in Wales, but who die outside Wales;
- d) persons who cannot be identified at their death;
- e) adults (those aged 18 or over) who do not have the capacity to understand and make a decision about objecting to donation;
- f) children and young people aged under 18 years of age.

The operation of the soft opt-out system for Wales

48. The Welsh Government will ensure there will be a robust and secure system for individuals to make an objection to donation of some or all of an individual's organs and tissues. The system will also ensure any objection of an individual to donate their organs and/or tissues is upheld, after death.

49. The soft opt-out system will enable individuals to change their minds, for example withdraw an objection, and to include people who move to Wales or who reach the age of 18.

The retention of the existing Organ Donor Register (ODR) for the people of Wales

50. The ODR is a confidential, computerised database which holds details of people who have signed up to become organ and tissue donors in the event of their death. The register is used after a person has died to establish whether they wanted to donate and if so, which organs and tissues.

51. The Welsh Government has considered carefully whether the existing ODR will continue to apply in Wales after the new legislation comes into effect. The value and importance of the existing ODR, and the commitment that individuals make by joining the register is recognised. For these reasons the Welsh Government will ensure the ODR continues to be available to individuals living in Wales.

52. The retention of the ODR for those individuals living in Wales who wish to use it, together with the new soft opt-out system, will provide benefits to individuals –

- a) the ability to record wishes in case an individual dies outside Wales, where the soft opt-out system will not apply;
- b) the ability to record an individual's wishes if they are not yet included within the soft opt-out system in Wales, for example they have only recently moved to Wales or they are under the age of 18;
- c) because organs and tissues are given to recipients across the United Kingdom, regardless of where they are donated, retention of the ODR in conjunction with the soft opt-out system will mean more organs and tissues available to those people who need them. This will improve the health and quality of life for people who need a transplant.

Maintaining records

53. NHS Blood and Transplant (an England and Wales Special Health Authority) hold and maintain the current ODR. Although the Welsh Government is committed to retaining the ODR (as set out above), we recognise it is not, currently, a record of all people who would be willing for their organs to be donated - in the last year alone, just over 67 per cent of donors in the UK were not on the ODR.

54. It is also not a record of people who do not wish their organs to be donated – indeed there is currently no formal mechanism for people who feel strongly against organ donation to register their objection. In the absence of such a mechanism it is impossible to be sure whether an individual's autonomy is being respected after death.

55. For these reasons the Welsh Government cannot use the existing ODR, as it is currently set up, to provide a safe and effective soft opt-out system.

56. The Welsh Government has therefore considered a number of record keeping options, to run alongside the existing ODR, which will ensure that an individual's autonomy is respected after death. These include:

- a) Option A – a register for Wales of persons who have not objected, and a register of persons who have objected;
- b) Option B – a register for Wales of only those persons who have not objected;
- c) Option C – a register for Wales of only those persons who have objected;
- d) Option D – no register(s) but a record of objection given to and held by a person's general practitioner.

57. Apart from option D, which relies on the GP record, there is a requirement for a register to be held. This indicates the need for a secure and confidential central register, which is accessible to clinicians after an individual's death.

58. The Welsh Government recognises that the record system put in place to support the operation of the soft opt-out system for Wales must be integrated into, and work cohesively with, the operation of the organ and tissue donation arrangements for the UK. Such arrangements could include adaption of the current ODR to accommodate the soft opt-out system in Wales.

59. The practical considerations for holding and maintaining any central register will be considered in light of the consultation responses to this White Paper.

How to make an objection to donation

60. The actual method(s) of making an objection will be influenced by whether a register is held, and if so the type of register (or registers). In any case, the Welsh Government will ensure any and all methods put in place enable an individual to make a confidential objection to donation in any easy and accessible manner.

61. Under the current arrangements an individual can register their intentions to donate all organs and tissues or to select specific organs or tissues. The Welsh Government recognises that individuals may be content to donate some of their organs and tissues, but not all.

62. The arrangements to be put in place for the soft opt-out system for Wales will enable an individual to opt-out of donating all organs and tissues, or to opt-out of donating some organs or tissues.

Keeping the soft opt-out system up to date

63. The soft opt-out system will need to be sufficiently flexible to accommodate changes after the main introduction of the new arrangements. Such changes will include:

- a) an individual changing their mind, for example previously objecting but now wishing to donate;
- b) people who move to or from Wales;
- c) young people reaching the age of 18.

64. The Welsh Government recognises the soft opt-out system which it introduces must acknowledge and enable these changes, so as to ensure that an individual's choices are respected and followed in the event of death.

65. These important operational considerations will be influenced by whether a register is held, and if so the type of register (or registers).

The safeguard provided by the role of the family

66. Currently where organ donation is being considered, a clinician will firstly check the ODR to ascertain whether an individual has indicated they would wish to be an organ donor. Regardless of whether an individual is on the register or not, clinicians will approach family members to ascertain the wishes and views of the deceased person about donation. This allows any evidence from the family of the individual's recent wishes to be understood.

67. Under the Human Tissue Act 2004 (the Act), and the associated Codes of Practice, clinicians approach relatives in the order that they are listed:

- spouse or partner;
- parent or child;
- brother or sister;
- grandparent or grand child;
- niece or nephew;
- stepfather or stepmother;
- half-brother or half-sister;
- friend of long standing.

68. The wishes of the deceased are given primacy under the Act, and the Welsh Government will not deviate from this important principle under the new legislation. Indeed the soft opt-out system will provide additional clarity on the individual's views, because objection cannot be recorded within the current system.

69. The Codes of Practice currently advise health professionals to sensitively encourage relatives to accept the deceased's wishes, whilst making it clear that the relatives do not have the right to override those wishes.

70. The Welsh Government is committed to a soft opt-out system of organ and tissue donation in which the views of relatives will be taken into account. Retaining the role of relatives in this way serves a number of purposes –

- a) it acts as an important safeguard: families may be aware of an unregistered objection;
- b) it recognises the doctor's duty of care towards relatives to relieve and not add to their distress and bereavement; and
- c) details obtained from relatives about the patient's medical and behavioural history can play an important part in the success of a transplant.

71. Under a soft opt-out system of organ and tissue donation, in conjunction with an extensive public awareness programme, individuals are far more likely to have discussed their views with their families and to have made their views clear prior to death.

72. The Welsh Government recognises the importance of the role of the family in a soft opt-out system. The wishes of the deceased will be respected and in order to safeguard these wishes family involvement is essential. We are seeking your views on the role of the family as part of this White Paper.

73. Whilst relatives will still be consulted, the burden of making the decision in the absence of any indication of the deceased person's wishes at such a difficult time will be reduced.

What the soft opt-out system will not change

74. The Welsh Government may only make legislation in relation to Wales. Therefore the soft opt-out system will apply in relation to Wales only.

75. The Welsh Government's policy intention is that the proposals:

- a) will not change the way patients are cared for (including the medical treatment they will receive) up to and including the time of death;
- b) will not change the way in which death is confirmed – there are very clear and strict standards and procedures for confirming death;
- c) will not include living donation of organs and tissues (namely, the transplantation of an organ or tissue from a living donor to a transplant recipient - often a friend or family member);
- d) will not change the way that organs and tissues are allocated by NHS Blood and Transplant;
- e) will not alter the clinical decision making for, and processes associated with, transplant;
- f) will not allow donated organs and tissues to be available for any purpose other than transplantation. The new system will not mean that donated organs and tissues may be used for purposes such as research, display or commercial use;
- g) will not remove an individual's opportunity to join the current Organ Donor Register.

76. The soft opt-out system that is being proposed for Wales is one in which the removal and use of organs and tissues is permissible unless the deceased objected during his or her lifetime. Individuals will have a formal mechanism for registering that objection. After death relatives will be involved in the decision making process around donation.

77. Such a system will improve the way individuals in Wales are able to set out their wishes for donation, and strengthen the position for those who do not wish to donate, whilst still ensuring that more organs and tissues are available for those who need them.

IMPLEMENTATION OF PROPOSED LEGISLATION

Impact assessment

Equality impact assessment

78. The Welsh Government is committed to making sure that as policies, strategies, action plans and legislation are developed, every effort is made to actively contribute to an environment that is free from discrimination. Part of this is about assessing the impact that policies and actions may have on the people of Wales, to make sure that the Welsh Government does not discriminate but takes every opportunity to promote equality and good relations.

79. The policy contained within this White Paper has had an initial equality screening assessment in line with the Welsh Government's Inclusive Policy Making practice. This initial assessment has found –

- a) high relevance of the policy in respect of race, faith, and human rights;
- b) medium relevance in respect of disability and age;
- c) no evidence of a specific impact of the policy with regards to sexual orientation, marriage and civil partnership, or gender and gender re assignment.

80. During the process of initial assessment it has been noted that patients from the same ethnic group are more likely to be a close match within the context of organ donation.

81. People of Asian or African-Caribbean descent are three to four times more likely than white people to develop end-stage renal failure and need a kidney transplant. Data from NHS Blood and Transplant identifies that in the UK people from Asian or African-Caribbean ethnic groups make up 23 per cent of the waiting list for kidney donation although they account for 8 per cent of the population (based on 2001 Census figures). Only 3 per cent of deceased donors are of Asian or African-Caribbean descent.

82. The Welsh Government will seek, through the consultation process on this White Paper, to have specific discussions with black and minority ethnic (BME) communities and faith groups.

83. A detailed Equality Impact Assessment will be developed and published by the Welsh Government as part of the introduction of future legislation. Consultees are invited to comment on the impact of the policy on the equality strands of:

- a) disability;
- b) race;
- c) gender and gender reassignment;

- d) age;
- e) religion and belief and non-belief;
- f) sexual orientation; and
- g) human rights.

Privacy impact assessment

84. A privacy impact assessment will assess the privacy implications of activities which involve the use of (or changes to the use of) personal data as defined by the Data Protection Act 1998.

85. Following consultation on this White Paper an initial screening under the privacy impact assessment will take place, so as to consider the privacy implications associated with making and recording any objection under the soft opt-out system.

Regulatory Impact Assessment

86. When the proposed legislation is laid before the National Assembly for Wales, the Welsh Government will provide an Explanatory Memorandum including a Regulatory Impact Assessment (RIA).

87. The RIA will set out the costs and benefits associated with achieving the proposed Bill's strategic objective of maximising the number of organs and tissues donated by patients in Wales.

88. When quantifying costs, the Regulatory Impact Assessment will seek to establish:

- a) who will bear any costs;
- b) any one-off costs (for example, setting up a register or initial public awareness campaigns);
- c) any recurrent costs (for example, costs associated with operating a register, or ongoing communication programmes); and
- d) any other costs.

89. An initial estimate of costs has been developed as part of the preparation for this White Paper. This initial estimate indicates that prior to implementation up to £2.85m will be required for training and communications.

90. Further work will be required to refine the recurrent operational costs in relation to the soft opt-out system, including any registers and record keeping systems.

Timetable

91. This White Paper is a consultation document and the Welsh Government is inviting views on the proposals by **31 January 2012**.

92. Following consideration of the consultation responses, a Bill will be brought forward by the Welsh Government and introduced into the National Assembly for Wales during 2012/13.

93. It is currently expected that there would be a lead-in period between the making of the legislation and the new soft opt-out system coming into force. Such a time period will enable the appropriate mechanisms and systems of operation to be established, and for the major public awareness campaign to be rolled out.

94. The lead-in period is likely to be two years, and therefore the earliest that the soft opt-out system will be in operation in Wales is 2015. Further details on the implementation programme will be set out in Explanatory Memorandum and RIA for the Bill when it is introduced.

Welsh Language provision

95. The soft opt-out system will comply with the requirements set out in the Welsh Language Act 1993, and any relevant provisions of the Welsh Language (Wales) Measure 2011 in force at the time.

Public awareness campaign

96. This White Paper has set out the need for, and importance of, a major public awareness campaign prior to the new soft opt-out system coming into effect. Fuller details of the proposals for such a campaign will be set out in the Explanatory Memorandum and RIA, however the early proposals include –

- out of home activity (e.g. billboards);
- extensive television, radio, press and online activity;
- community activity;
- stakeholder engagement; and
- printing and distribution of bi-lingual leaflet to all Welsh households (with additional copies for outlets such as GP surgeries).

97. The public awareness campaign will be extensive both in its use of different forms of media and in its duration (prior to and after enactment of legislation) to ensure that all those people who wish to opt - out know how to do so.

CONSULTATION QUESTIONS

As part of the consultation process the Welsh Government is seeking responses on particular aspects of the policy proposals, however respondents are invited to provide additional comments and evidence on the proposal as a whole.

Persons who will be included in the soft opt-out system

1. The White Paper sets out individuals must have lived in Wales for a sufficient period of time before being included within the soft opt-out system.
 - a) What factors should be taken into account when determining whether an individual 'lives in Wales'?
 - b) What should that period of time be?
2. Do you agree discussions between clinicians and family in the event of an individual's death, will identify and safeguard those who lack capacity?
3. Do you agree that the soft opt-out system for Wales should only apply to persons aged 18 years and over? If not, why?

The operation of the soft opt-out system for Wales

4. Do you agree with the retention of the existing Organ Donor Register to be operated in conjunction with the soft opt-out system?
5. In relation to the record keeping options for the soft opt-out system –
 - a) Which of the suggested options do you prefer? (See paragraph 56 of the White Paper.)
 - b) Are there other options you feel would provide an effective and secure system?
6. What is the role of the family in safeguarding the wishes of the deceased?

Implementation

7. How can the Welsh Government ensure that the public awareness campaign is effective?
8. The Welsh Government would welcome your views on the potential impact of the proposed soft opt-out system for the Welsh Language, race, faith, disability, age, sexual orientation, gender, gender reassignment, marriage or civil partnership.
9. The Welsh Government has asked a number of specific questions; if you have any related issues which have not been specifically addressed, please record them here.