

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Welsh Government's consultation on the Draft Human Transplantation (Wales) Bill.
2. As the statutory regulator responsible for the consent provisions within the Human Tissue Act 2004 (HT Act), the HTA is charged with ensuring that appropriate and valid consent is in place when organs and tissue are donated from deceased and living people for the purpose of transplantation.
3. The HT Act covers England, Wales and Northern Ireland and requires consent for a number of activities, including organ donation, to be an active and positive act.
4. There are similar provisions in Scotland under the Human Tissue (Scotland) Act 2006, and while the word "authorisation" is used in place of "consent", there is a requirement that this is a positive act and the principle is the same.
5. There is further discussion of the proposal put forward by the Welsh Government below. However, the essence of the proposal is that for people who both live and die in Wales who did not make a decision in life, the presumption will be that they wished to donate their organs and tissue after death.
6. When the word "organ" is used in this document, it should be read to include organs, part organs and tissue.
7. The HTA has responded to the Welsh Government's previous consultations on the introduction of a soft-opt out system for organ donation, these responses can be found [here](#).

The proposal

8. It is of value to set out the main features of the Welsh Government's proposals in order to place this response in context.
9. The draft legislation introduces the concepts of deemed and express consent. Express consent is identical to the active consent requirement of the HT Act. It is, in the first instance, the consent of the person themselves in life, if that does not exist the consent of a nominated representative, and if there is not a nominated representative, then the consent of a person in a qualifying relationship to the donor.
10. Under the draft legislation express consent will be required for:
 - a. Living organ donation
 - b. Deceased organ donations from children
 - c. Deceased organ donations from adults who lack the capacity to consent
 - d. Deceased donations from people who live and die in Wales but have not been resident for six months or more
 - e. Deceased organ donations from people who die in Wales but who are not resident in Wales
 - f. Deceased organ donations from Welsh residents who die somewhere else in the UK
11. Under the draft legislation, when an adult Welsh resident who had the capacity to consent dies in Wales, and had registered either a wish to be considered as an organ donor, or their wish not to be an organ donor, this will be acted upon, if possible.
12. If such a person has not registered either a yes or a no on the Welsh register, then their consent will be deemed. This means that the starting point of the conversations which will be held with the potential donor's family and friends is that they wished to donate. At present, when there is no recorded wish the family are approached to ask whether they are aware of the wishes of the deceased.
13. The fact that the family will still be involved in the process under the Welsh Government's proposals means that this key safeguard is still in place. Although the family will not have the right to veto the donation if there is a recorded yes or deemed consent in place, if they are able to provide evidence that would satisfy a reasonable person that the deceased did not wish to be a donor this will be accepted. It is proposed that if a family does not go ahead

with a donation when consent has been deemed, then they will be asked to fill in a form confirming this and providing reasons why this is the case.

14. If a person has recorded a no on the Welsh register, their family will not be approached and donation will not be considered.
15. It should be noted that the current legislation (the HT Act) does not give families a veto over the deceased's recorded wishes. When a person has registered on the Organ Donor Register (ODR), and subsequently dies, the role of the family is to let the Specialist Nurse for Organ Donation (SNOD) know whether they had changed their mind, and to provide the medical and social information necessary for the donation. The existing legislation does not allow for a family to stop a donation because they do not want it to go ahead.
16. In reality, however, the duty of care the surgical and medical teams have to the family of the deceased means that a donation will not proceed without their support. This matter has received recent media coverage,¹ and the HTA will follow with interest whether the proposed changes in Wales have any impact on the status quo of the family in effect being able to veto the wishes of the deceased.
17. While a great deal of the media coverage on the Welsh Government's proposals has referred to presumed consent, the system which is proposed does not presume consent and then move directly to donation; the family will still be involved and a discussion will be held with them before any action is taken.
18. In fact, a 2012 paper published in *Transplantation*² noted that there is not a "pure" system of presumed consent in operation anywhere in the world. That is to say that no country moves to retrieve organs without first consulting the family.
19. The HTA acknowledges that there are areas which require further consideration prior to the implementation of the proposed system. However, the operational process as laid out in the consultation document does not differ significantly from that which operates at present, in the sense that the register will be consulted and a conversation will then be held with the family.

¹ [Daily Mail](#), 8 August 2012

² http://journals.lww.com/transplantjournal/Abstract/2012/01270/Potential_Limitations_of_Presumed_Consent.2.aspx

20. What will change is that there will be a new Welsh register which will record both wishes to donate and wishes not to donate, and that where the deceased has not made a decision in life, their family will be approached on the basis that they wished to be a donor. This means that in circumstances where consent is deemed, the principle that consent should be active will no longer apply.
21. It is planned that the draft legislation will be laid before the Welsh Assembly in December 2012, with the legislation receiving Royal Assent in summer 2013. It is then intended that there will be a two year lead-in period, with implementation in 2015.

The role of the HTA

22. As a statutory regulator, it is not the role of the HTA to either support or object to the proposals of the Welsh Government, which is constituted of the elected representatives of the Welsh people.
23. It is the role of the HTA to provide advice and guidance as required, and this consultation response document seeks to highlight the parts of the proposal which may require further consideration and development. This advice and guidance is based on the experience the HTA has gained since it was established in 2005, and on the provisions of the HT Act as it currently stands.
24. The HTA notes the ethical discussions on the Welsh Government's proposals. However, as a statutory regulator it is outside the remit of the HTA itself to participate in such discussions.
25. The Explanatory Memorandum provided by the Welsh Government states at paragraph 55 that changes will be required to the HTA's Code of Practice two on the donation of solid organs for transplantation, and that a draft of this document may be available to coincide with the laying of the Bill before the Assembly later this year. The HTA advises that due to the resource required in drafting a code of practice, the broad consultation which is necessary, and the in-depth legal review, it is very unlikely a draft document will be available for the Assembly's consideration in December 2012. At this stage it may be possible to provide an outline of the additional guidance which will ultimately be contained in a code of practice.
26. The HTA believes it would be prudent that resource is only used for drafting a code of practice on the basis of approved legislation, and not on draft legislation which will be subject to change as it passes through the stages of Assembly scrutiny.
27. As an opt-out system for organ donation is untested in the UK, the HTA is not yet in a position to accurately quantify the level of resource required to support the Welsh Government in the introduction of such a system. Therefore, at this stage it cannot be stated with confidence that the HTA will be able provide the level of support required within existing staffing levels.
28. It will also be necessary for the HTA to audit against different consent provisions in Wales and the rest of the UK under the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

29. The HTA will continue to work with DH and the Welsh Government to assess the level of support required, and how this will be delivered.

The views of HTA stakeholders

30. The HTA discussed the Welsh Government's proposals and consultation at its annual public meeting held on 10 July 2012. The papers and minutes of the meeting can be found [here](#).
31. At the meeting a number of the HTA's stakeholders, including Patient Concern and people who were directly affected by the organ retention scandal of the late 1990's, both as professionals and bereaved families, strongly put forward their view that the proposals amounted to an erosion of the principle of active consent which is at the core of the HT Act. They believe that in moving to a soft opt-out system the Welsh Government is removing the primacy of the individual's consent in life, and could expose the risk that organs or tissue may be removed without the consent of the individual or their family.
32. As such strong representations have been made to the HTA on the proposals, it is considered vital that they are represented in this response document in order to ensure the Welsh Government is aware of the range of views which exist.
33. The HTA has urged these stakeholders to respond to the consultation, and have gained the approval of those referenced above to include their concerns.

Areas for further consideration

34. The HTA would highlight the following three areas as those which require further consideration and development, and which will be key to the effective implementation and operation of the proposed system.

Communications

35. The commitment made in the consultation document to an effective and sustained communications campaign is noted by the HTA. Communication will be vital in ensuring that every person living in Wales and the bordering counties is aware of the proposed system and how it will affect them. In order for the individual's decision to remain paramount they must be aware of the action they are required to take, if any, to make their views known.

36. Communication with all Welsh residents and those living in the border counties will be important, and attention should be given specifically to those groups who are regarded as being hard to reach. These include those people whose first language is not English or Welsh, and also those living in deprived areas.

37. It will be important to develop a communications plan which ensures people who move to Wales are made aware of the system soon after they become resident, in order to allow them sufficient time to make a decision and, if necessary, record their wishes.

38. The HTA considers that the planned communication with every Welsh resident six months prior to their eighteenth birthday will be important to ensure that there is time for these young people to make an active decision prior to deemed consent applying to them.

39. Young people are widely considered to be challenging to engage with on such matters, and the HTA would encourage the Welsh Government to explore a wide range of channels in order for there to be confidence in the proposed system.

40. Any risk of a particular group or groups of Welsh residents being left behind on this matter due to poor communication must be actively addressed by the Welsh Government. Without an effective, comprehensive, targeted and continued communications campaign the proposed system cannot be said to hold the decision of the individual in life as a core principle. Indeed, without proper communication an individual may not be in receipt of the information

they require to know what their silence on the matter of organ donation after their death will be considered to mean.

41. In previous responses to the Welsh Government's consultations on an opt-out system for organ donation, the HTA has stressed the importance of a continuous communications campaign. Such a campaign will be critical in ensuring that every Welsh person is aware of whether or not the system affects them, and what action they need to take. If the focus on this continuous communications campaign is lost, or funding is either withdrawn or reduced, then there is a significant risk that people will not be properly informed, leading to the whole system being undermined.
42. The HTA has been invited to sit in an advisory capacity on the Welsh Government's Communications sub-group on this matter, and welcomes this opportunity.

Cross-border issues

43. The HTA believes that there is still work to be done on the cross-border issues which arise from the proposed system.
44. The introduction of a register for Welsh residents which records both wishes to donate, and wishes not to donate, means that there will be two different registers operating across the UK. In Wales an individual will be able to record a yes to all organs, a yes to some organs, or an outright no. In the rest of the UK an individual will be able to record a yes to all organs, or a yes to some organs, they will not be able to register a no.
45. Operationally this poses challenges as under the HT Act it is the wishes of the individual immediately before they died which are held as primary, and therefore if these wishes are recorded on the Welsh register they should be acted on, no matter where the individual dies. This means that for Welsh residents who die outside Wales, the SNOD will be required to check the Welsh register and act on the recorded wishes, if there are any. In fact, it may be prudent that the Welsh register is checked for every donor, as it may not be clear if they had ever been resident in Wales, and by checking both registers the risk that the "wrong" information is relied upon is limited. Therefore all SNODs must have access to both the Welsh register and the ODR and be in a position to easily establish whether a person is on either or both registers, and which record is most recent. This information will need to be quickly ascertained, most often in the middle of the night, and its accuracy must be guaranteed.

46. The proposal also states that individuals will be able to record their wishes on the new Welsh register prior to implementation of the soft opt-out system. As this recording will in effect form the last recorded wishes of the individual, it is vital that these are made available to SNODS in order to ensure compliance with the HT Act.
47. These are just two of a number of issues which may arise from the fact that there are likely to be two registers, and the HTA would urge the Welsh Government to investigate these fully in partnership with NHS Blood and Transplant (NHSBT) which is responsible for both the existing ODR and is the body proposed to establish and administer the new Welsh register.

Post implementation review

48. The consultation document commits to a thorough and on-going post implementation review and the HTA suggests that this seeks to highlight both successes and challenges. The HTA notes that both the Scottish Government and Northern Ireland Assembly³ have expressed interest in the Welsh Government's proposals, and as such the post implementation review may form part of the basis of policy decisions in other parts of the UK. This unique opportunity to share the experience of one country of the UK with others should not be lost, and investigation of the true outcomes for all involved from donor families, to recipients and clinical staff will be key to the wider understanding of how such a system operates.
49. The consultation document puts forward a figure of 45 more organs becoming available each year as a result of this legislative change. The fixed costs associated with the proposal which the Welsh Government will incur are given as approximately £5m over ten years. There will be costs associated with the proposal which other organisations will incur. The Welsh Government estimates that it will be required to provide NHSBT with £2.88m each year for the new Welsh register. All other costs are expected to be met from existing NHS budgets. As part of the post implementation review the HTA considers it important that these figures are revisited to establish how realistic they were, and if there is a significant variation, either up or down, that this is explored further.

³ [Holyrood](#) magazine, 30 January 2012, and [Belfast Telegraph](#), 10 October 2011

Conclusion

50. The HTA acknowledges that deceased organ donation is an ethically complex matter; and what is acceptable to one person maybe unconscionable to another.
51. The Welsh Labour Party holds the majority of seats in the Welsh Assembly and their manifesto⁴ included a commitment to implement a soft opt-out system for organ donation; this consultation marks a further step towards this.
52. It is not for the HTA itself to comment on the principles of the proposal, but rather to offer advice and guidance to ensure the Welsh Government has the information it needs.
53. This response provides such advice and guidance and the HTA urges the Welsh Government to give further consideration to the areas highlighted in paragraphs 34 to 49 above.
54. The key message the HTA wishes the Welsh Government to take from this response is that communication and collaboration are vital. During the development phase this primarily means communication with stakeholders on the proposals and a continued dialogue with all interested parties, most notably those who oppose the proposal.
55. During the implementation phase which is likely to be from 2013 to 2015, communication with Welsh residents will need to be effective, targeted and consistent, and collaboration with organisations such as the HTA and NHSBT will be necessary to make sure all risks are managed and addressed.
56. Finally, post implementation the importance of continued communication with Welsh residents cannot be overstated, as it will be the efficacy of this which will allow the Welsh Government to state that the wishes of the individual in life remain paramount, and that no erosion of this principle has occurred.

⁴ P53, <http://www.welshlabour.org.uk/uploads/welsh-labour-manifesto.pdf>

Consultation questions

Have the concepts of deemed consent and express consent been explained clearly enough?

57. The HTA considers that both concepts have been explained clearly.

Is the role of the family clear?

58. The role of the family is generally made clear. However, the HTA considers that more information should be provided on the requirement that information which would satisfy a reasonable person must be provided by a family to prove that the deceased person had changed their mind. There should be certainty as to what kind of information is required to satisfy the reasonable person test. For instance, it should be made clear whether a higher test will be set if a family states that a registered yes has become a no, rather than deemed consent through silence having changed to a no.

Are the arrangements for the registration of wishes clear?

59. The HTA considers the arrangements for the registration of wishes to be as clear as they can be at this early stage in the commissioning of a new Welsh register. The HTA urges the Welsh Government and NHSBT to work together on the development of this register, and to widely publish information about how it will operate at the first possible opportunity.

Are the arrangements for establishing residency clear?

60. The HTA notes that the arrangements for establishing residency have developed significantly since the Welsh Government's consultation on this matter which ended in January 2012. There will, however, need to be collaborative work undertaken with NHSBT and SNODs to establish how this will operate practically.

Does the Equality Impact Assessment properly set out how the legislation will affect different sections of society, including children and people who lack capacity?

61. The HTA considers that the Equality Impact Assessment adequately addresses these matters.

The outline for the communication plan is shown in the Explanatory Memorandum. Do you feel reassured that the Welsh Government is planning the public information campaign thoroughly?

62. The HTA notes the Welsh Government's outline communication plan, and believes that the successful delivery of this will be key to the implementation of a soft opt-out system for organ donation.

Any other comments not addressed by the questions above?

63. The HTA has included further comments in the body of the response above.