

## **NORTHERN IRELAND ASSEMBLY: HUMAN TRANSPLANTATION BILL: CALL FOR EVIDENCE**

### **RESPONSE FROM THE WELSH GOVERNMENT: DECEMBER 2015**

1. This paper sets out the background to the development and implementation of the Human Transplantation (Wales) Act 2013. The legislation came into effect in Wales on 1 December 2015 and from that date introduced a “soft opt out” system for consent to deceased donation for the purposes of transplantation.
2. This new system means that people living in Wales are regarded as having no objection to organ donation after death, unless they have indicated otherwise. This is called “deemed consent”. The law contains a safeguard for relatives and friends of long standing to object to deemed consent on the basis that they know the deceased would not have consented.
3. This paper is set out in two parts, covering the development of the new law and the implementation of the legislation.

### **Development of the Human Transplantation (Wales) Act 2013**

#### **Rationale**

4. Despite the very welcome improvements in organ donation and transplantation since the Organ Donation Task Force report of 2008, there continues to be a persistent shortage of organs for transplant in the UK. Advances in professional practice following the Task Force recommendations, including more systematic identification, testing and referral of potential donors, resulted in a 50 per cent increase in the donation rate between 2008 and 2013.
5. Although more people have agreed to donate organs, this is largely because more people have been asked. During this period the proportion of families agreeing - the consent rate - has remained largely unchanged in many parts of the UK, and potential donors are being lost. Tackling the issue of consent has been identified as one of the key areas for action in the *Taking Organ Donation and Transplantation to 2020* strategy which followed on from the Task Force recommendations. The 2020 strategy highlights that the UK needs a transformation in donor and family consent to match the transformation already underway in NHS organ donation and transplantation services. It calls for a revolution in public attitudes and behaviour towards organ donation so that the UK can match those countries which perform best.
6. The Welsh Government believes that a change in the law to an opt out system is likely to deliver that revolution in attitudes and behaviour. Surveys consistently suggest that nine in ten people when asked say they support organ donation. However, only around three in ten have registered their decision on the Organ Donor Register. We believe that having a system which views people as having no objection to organ donation unless they

have said otherwise is a more positive position and in line with what the majority already say they would want.

### Consultation in Wales

7. Significant consultation took place in Wales prior to the introduction of the Bill. Debate had been ongoing since 2008, following a campaign by Kidney Wales Foundation in 2007 calling for the introduction of an opt out system. During the 2011 Welsh Assembly elections, three of the political parties included in their manifestos their intention to introduce a soft opt out system for consent to organ donation. A White Paper followed in November 2011, outlining the broad principles which the policy would follow and asking for comments on how such a system should work. This consultation attracted just over 1,200 responses. Consultation on a draft Bill took place between June and September 2012 and almost 3,000 responses were received. The final Bill was laid before the Assembly on 3 December 2012 having taken into account comments received during the consultation.
  
8. A representative survey of the Welsh public prior to introduction showed a considerable level of support for a change in the law, with almost half saying they were in favour and less than a quarter saying they were against with the remainder needing more information to decide. Public support for the change has increased significantly between June 2012 and June 2015 whilst those against or needing more information to decide have decreased markedly.

Response	June 2012	June 2013	November 2013	June 2014	November 2014	June 2015
In favour of the change	49	61	57	63	64	67
Against the change	22	17	16	18	17	14
Need more information to decide/don't know	29	22	27	18	20	19

### International evidence

9. The Welsh Government carried out a review of the international evidence and this was published when the Bill was introduced. The review concluded that the existing international evidence suggests that an association exists between presumed consent legislation and increased organ donation rates. It also looked at experimental literature and concluded that this also provides evidence for a mechanism through which presumed consent might increase organ donation, through the influence of the default position. Based on the international evidence, we concluded that a change to an opt out system could result in a 25 to 30 per cent increase in the number of donors.

## **Format of the legislation**

10. The Human Transplantation (Wales) Act 2013 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). As a result, the 2013 Act restates, for Wales, certain sections of the 2004 Act directly related to consent for the purposes of transplantation. Other aspects of the 2004 Act continue to apply in Wales. We note the Northern Ireland Human Transplantation Bill has adopted a similar approach.

## **Legislative scrutiny**

11. The Bill underwent detailed and robust scrutiny in the National Assembly for Wales between January and July 2013. The Health and Social Services Committee took evidence from a wide range of stakeholder and experts. Several amendments were made to the Bill during its passage in order to address points raised during scrutiny. The amendments included:

- a new provision for excluded relevant material (so called novel forms of transplantation) including powers for Welsh Ministers to specify in Regulations which organs and tissues to be excluded from deemed consent;
- a new section to allow children to appoint representatives in line with the direction of travel set out in European law and the Rights of Children and Young Persons (Wales) Measure 2011 and
- a clear right for relatives and friends of long standing to object to consent being deemed on the basis that they know the deceased would not have consented. The objection must be based on the known views of the deceased and not on the views of the relative or friend. The information provided should lead a reasonable person to conclude that the person objecting did indeed know the most recent views of the deceased.

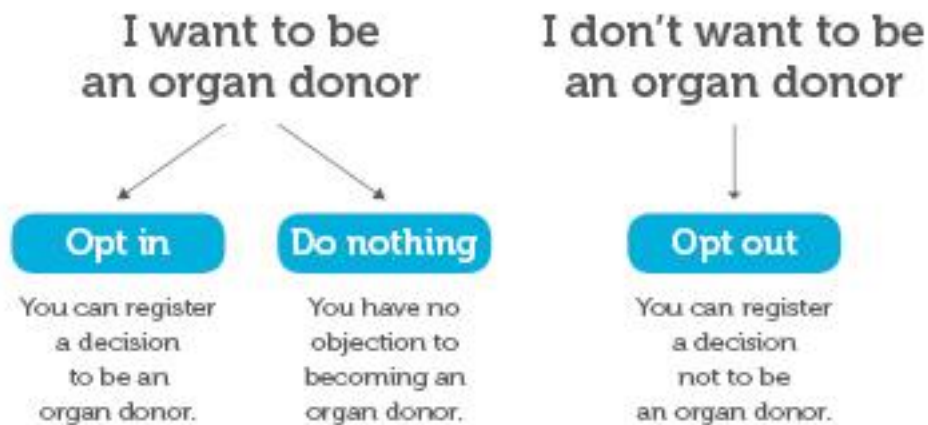
12. The Bill was passed by the National Assembly for Wales on 2 July 2013 following one of the longest debates ever held in the Assembly. The final vote was 43 in favour, 8 against and 2 abstentions.

## **Implementation of the Human Transplantation (Wales) Act 2013**

### **Communications with the public**

13. Whilst the majority of the provisions in the Act did not come into force until 1 December 2015, certain sections commenced on Royal Assent, most notably Section 2, which relates to Welsh Ministers' duty to publicise the arrangements contained within the Act.

14. A two year communications campaign began on 1 December 2013 focussing on a mass media advertising campaign and bespoke engagement work with specific audience groups who may not be engaged in mainstream media. The campaign was rolled out in a strategic phased approach. The messages change over time to reflect key milestones in the wider implementation of the Act. Within each phase, there were a number of advertising “bursts” and distinct messages.
15. The choices presented in the communications campaign are:



16. Two reports have been laid before the Assembly (in October 2014 and December 2015) detailing the communication and engagement work undertaken. The links to these reports are shown below.

[Human Transplantation \(Wales\) Act 2013 - annual communications report: October 2014](#)

[Human Transplantation \(Wales\) Act 2013 - annual communications report: December 2015](#)

17. Additional bespoke work has been carried out with faith groups and black and ethnic minority (BAME) communities in Wales. Materials have been produced in numerous formats including BSL, Braille, Easy Read, Large Print and in several languages. A budget of £3.4 million was allocated to the communications and engagement work between 2013 and 2016.

### **Organ Donor Register**

18. The Organ Donor Register has been redeveloped by NHS Blood and Transplant in order to support the registration of opt out decisions. Wales met half of the development costs and the other nations agreed to fund a share proportionate to their populations. The new Organ Donor Register was launched on 15 June 2015. It is a much more robust system than the

previous Organ Donor Register, with improved functionality, resilience and future-proofing. At the time of writing this paper, around 105,000 people in Wales had opted out (approximately 3 per cent of the Welsh population). This compares with 1,084,000 who remain opted in.

### **Code of Practice and subordinate legislation**

19. The Human Tissue Authority developed and consulted on a draft Code of Practice in late 2013 and this has been used to develop training for staff involved in organ donation in Wales. The Code of Practice was approved by the National Assembly for Wales on 6 October 2015 and passed through Parliament on 26 November 2015.
20. In March 2015, the UK Government took through Parliament the Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2014. This Order made an amendment to the Human Tissue Act 2004 to ensure that organs and tissues donated in Wales under deemed consent would be able to be used for transplantation activities in England and Northern Ireland. It also amended the Act to ensure that appointed representatives made under the Human Transplantation (Wales) Act would be recognised in England and Northern Ireland. These amendments ensured the preservation of the effective cross-border flow of organs and tissues within the UK.
21. The National Assembly for Wales also approved a suite of subordinate legislation on 6 October 2015 covering excluded materials, appointed representatives and living adults who lack the capacity to consent to transplantation activities.

### **Staff training**

22. NHS Blood and Transplant has led on the training of clinical staff both on the operation of the new Organ Donor Register and the detail of the Welsh legislation. Whilst the training has been most intense for those working in Wales, it has extended to the whole of the UK in order that all clinical teams are aware of the Welsh law. The training has consisted of presentations and filmed scenarios focussing on the donation conversation. The Welsh Government produced a factsheet for healthcare professionals that was sent to all organ donation committees in the UK and to GPs and clinical staff in Wales.

### **Evaluation**

23. A full programme of research and evaluation has taken place alongside the development and implementation of the legislation, as follows:
  - *Survey of public attitudes towards organ donation* – a baseline survey was carried out in 2012 and then repeated at intervals in order to allow public attitudes, awareness and understanding of the organ donation system in Wales to be monitored. Smaller qualitative studies were also carried out in

early 2012 and again in October 2014 with a number of focus groups and via in-depth interviews with the public across Wales;

- *Opt out systems of organ donation: international evidence review* – this review was carried out in 2012 with the aim of updating the existing systematic review conducted by the University of York in 2008 (Rithalia et al., 2008) which examined the impact of ‘opt-out’ (or ‘presumed consent’) legislation on organ donation rates. The report also reviewed literature published since 2008 assessing the impact of ‘opt-out’ legislation on organ donation rates, in addition to recent public opinion surveys and experimental studies relevant to presumed consent for organ donation;
- *The role of families in organ donation: international evidence review* – this review was carried out in 2012 to provide a general overview of extant research involving the families of potential organ donors and the factors involved in family consent rates, including the importance of familial discussions;
- *Researching the views of specialist nurses and clinical leads for organ donation in Wales* – this research was carried out in August 2013 and updated in June 2015 and aimed to explore the perceptions of current working practices and to establish the expectations, attitudes and any concerns regarding the implementation of an opt out system;
- *Survey of NHS Wales staff* – this report was published in July 2014 and looked at general awareness of the new law across a range of staff groups, the impact on staff roles and how confident staff would be in answering questions about the new system. A second phase will take place in 2016;
- *Impact evaluation of the Human Transplantation (Wales) Act* – the aim of this evaluation will be to assess the implementation of the Act and its impact on donation rates. An analysis plan was published in June 2015 and the final report will be published in late 2017. The evaluation is being undertaken by Professor Roy Carr-Hill of the Institute for Education, University College London and Richard Glendinning and Sarah McHugh of GFK NOP. The impact evaluation will use existing routine data and the above evaluation strands to provide a robust practical measurement of the impact of the Act, against the backdrop of what is happening elsewhere in the UK that might be influencing donation rates.