



The Scottish Parliament
Pàrlamaid na h-Alba

HEALTH AND SPORT COMMITTEE

AGENDA

30th Meeting, 2018 (Session 5)

Tuesday 20 November 2018

The Committee will meet at 10.00 am in the James Clerk Maxwell Room (CR4).

1. **Human Tissue (Authorisation) (Scotland) Bill:** The Committee will take evidence on the Bill at Stage 1 from—

Richard Glendinning, now with Ipsos Mori and former Director of Social Research and Lead Researcher on the Evaluation of the Human Transplantation (Wales) Act, Growth for Knowledge (GfK UK);

Dr Frank Atherton, Chief Medical Officer/Medical Director, NHS Wales, Welsh Government;

Dr Katja Empson, Regional Clinical Lead for Organ Donation South Wales, Cardiff and Vale University Health Board.

2. **European Union (Withdrawal) Act 2018:** The Committee will consider a proposal by the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposals-

The Food and Feed Imports (Amendment) (EU Exit) Regulations 2018;
The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2018;

The Sprouts and Seeds (EU Exit) Regulations 2018;

The Animal Feed (Amendment) (EU Exit) Regulations 2018;

The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment) (EU Exit) Regulations 2018.

3. **European Union (Withdrawal) Act 2018 (in private):** The Committee will consider a proposal by the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposals—

The Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (EU Exit) Regulations 2018;
The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2018;
The Official Controls for Feed, Food and Animal Health (Amendment) (EU Exit) Regulations 2018;
The Food and Feed (Chernobyl and Fukushima Restrictions) (Amendment) (EU Exit) Regulations 2018; and
The Novel Food (Amendment) (EU Exit) Regulations 2018.

4. **Human Tissue (Authorisation) (Scotland) Bill (in private):** The Committee will consider the evidence heard earlier in the meeting.
5. **Health and Care (Staffing) (Scotland) Bill (in private):** The Committee will continue its consideration of a draft Stage 1 report.
6. **Scrutiny of NHS Boards - NHS Dumfries and Galloway (in private):** The Committee will consider a draft follow-up letter to NHS Dumfries and Galloway.
7. **Scrutiny of NHS Boards - NHS Forth Valley (in private):** The Committee will consider its next steps.

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The papers for this meeting are as follows—

Agenda item 1

PRIVATE PAPER

HS/S5/18/30/1 (P)

Witness written submission

HS/S5/18/30/2

Agenda item 2

PRIVATE PAPER

HS/S5/18/30/3 (P)

Agenda item 3

PRIVATE PAPER

HS/S5/18/30/4 (P)

Agenda item 5

PRIVATE PAPER

HS/S5/18/30/5 (P)

Agenda item 6

PRIVATE PAPER

HS/S5/18/30/6 (P)

Agenda item 7

PRIVATE PAPER

HS/S5/18/30/7 (P)

HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM DR FRANK ATHERTON, CHIEF MEDICAL OFFICER FOR WALES

Response from the Welsh Government: November 2018

1. The Welsh Government is pleased to assist the Scottish Parliament's Health and Sport Committee in its scrutiny of the Human Tissue (Authorisation) (Scotland) Bill.
2. 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.
3. This 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.
4. This paper is set out in two parts, covering the development of the law and the implementation of the legislation, including its effectiveness. We also offer the Welsh Government's observations on the Human Tissue (Authorisation) (Scotland) Bill in particular any similarities or differences with the Welsh legislation.

Part 1: Development of the Human Transplantation (Wales) Act 2013

Rationale

5. Despite the very welcome improvements in organ donation and transplantation since the Organ Donation Task Force report of 2008, there continued 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.
6. Although more people agreed to donate organs, this is largely because more people were asked. During this period the proportion of families agreeing - the consent rate - remained largely unchanged in many parts of the UK, and potential donors were being lost. Tackling the issue of consent was 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 highlighted that the UK needed a transformation in donor and family consent to match the transformation already underway in NHS organ donation and transplantation services. It called for a revolution in public attitudes

and behaviour towards organ donation so that the UK could match those countries which perform best.

7. The Welsh Government believed that a change in the law to an opt out system was likely to deliver that revolution in attitudes and behaviour. Surveys consistently suggested that nine in ten people when asked said they supported organ donation. However, only around three in ten 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

8. 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.
9. 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 increased significantly between June 2012 and June 2015 whilst those against or needing more information to decide 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

10. 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 suggested that an association exists between presumed consent legislation and increased organ donation rates. It also looked at experimental literature and concluded that this also provided 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

11. 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.

Legislative scrutiny

12. 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:

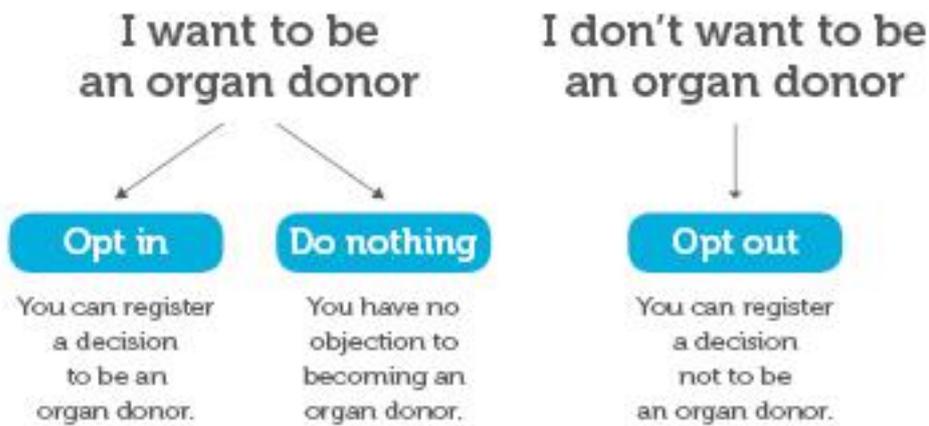
- a new provision for excluded relevant material (so called novel forms of transplantation) including powers for Welsh Ministers to specify in Regulations which organs and tissues to be excluded from deemed consent;
- a new section to allow children to appoint representatives in line with the direction 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.

13. 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.

Part 2: Implementation of the Human Transplantation (Wales) Act 2013

Communications with the public

14. 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.
15. 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 changed 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.
16. The choices presented in the communications campaign were:



17. Subsequently, four reports have been laid before the Assembly (in October 2014, December 2015, December 2016 and December 2017) detailing the communication and engagement work undertaken. The link to the latest report is shown below.

<https://beta.gov.wales/sites/default/files/publications/2018-07/171204-organ-donation-wales-communications-activity-2017.pdf>

18. 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. The budget for all organ donation communications activity in 2017-18 increased to £350k to accommodate the advertising campaign (increased from £200k in 2015-16).

Organ Donor Register

19. The Organ Donor Register was redeveloped by NHS Blood and Transplant in order to support the Welsh legislation and to allow 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 redeveloped 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 182,850 people in Wales had opted out (approximately 6 per cent of the Welsh population). This compares with 1,273,919 who have opted in (approximately 41% of the Welsh population).

Code of Practice and subordinate legislation

20. The Human Tissue Authority (HTA) developed and consulted on a draft Code of Practice in late 2013, and this was 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. The Code was updated in July 2017 to make minor technical changes resulting from the HTA's revision of all its Codes of Practice.

21. 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.

22. 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

23. 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 which was sent to all organ donation committees in the UK and to GPs and clinical staff in Wales.

Evaluation

24. 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 was undertaken in November 2016 and January 2017;
- *Impact evaluation of the Human Transplantation (Wales) Act* – the aim of this evaluation was 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 published 1 December 2017. The evaluation was 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 used 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. The report concluded that a longer period of time is needed to draw firmer conclusions around the impact of the change in the law.

Comparison of the Human Tissue (Authorisation) (Scotland) Bill and the Human Transplantation (Wales) Act 2013

25. We are aware that the Committee may find it helpful to receive our observations on the Human Tissue (Authorisation) (Scotland) Bill and any similarities or differences with the Welsh legislation.

Similarities

26. We believe the operational format to be largely consistent with the Human Transplantation (Wales) Act 2013 and the Human Tissue Authority Codes of Practice. This is important in terms of the practical application of the law by clinical teams and NHSBT. The use of the term 'deemed authorisation' appears to equate to the term 'deemed consent' in the Welsh legislation. There are also provisions for defining excluded relevant materials in regulations, as there are in the Welsh Act.

Differences

27. The Scottish Bill does not provide for the appointment of an authorised representative to make an organ donation decision on behalf of the patient, whereas the Welsh legislation provides for the ability to appoint a representative. This is a difference which already existed between the Human Tissue (Scotland) Act 2006 and the Human Tissue Act 2004. In Wales we chose to replicate the existing provision from the Human Tissue Act 2004 and extended it to children.
28. The age at which deemed authorisation applies is 16 compared to 18 in Wales.
29. The Scottish Bill sets out in detail the arrangements for pre death procedures. The Welsh legislation does not do this but instead 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.

Effectiveness of the Welsh legislation

Consent rates

30. NHS Blood and Transplant analyses the effect of Welsh legislation on consent/authorisation rates. NHSBT has collected cumulative data on consent rates in Wales and compared them to those in England. They report on a quarterly basis using the accumulating data to formally test whether there is a significant difference between the two underlying consent rates.
31. The latest data (2018/19 Quarter 2) shows that DBD consent rates have for the first time, shown a statistically significant increase in Wales (88.2%) when compared to England (73.3%). For the last two quarters, DCD consent rates in Wales have also improved, with DCD consent rate in Wales 68% compared to England 59.8%. NHSBT will continue to monitoring quarterly both DBD and DCD consent rates to ensure the improvement in the DBD consent rate in Wales is

sustained and to complete its assessment of the DCD consent rate. They will also undertake a multivariable analysis to determine whether the observed increase in DBD consent rates in Wales is a result of the introduction of deemed consent once other factors known to influence consent rates have been accounted for.

Number of donors

32. As mentioned above, our initial view was that, based on the international evidence, a change to an opt out system could result in a 25 to 30 per cent increase in the number of donors, equating to an additional 15 donors. We did not attach a timeframe to this but we can now see that since the introduction of the new law, the number of deceased donors in Welsh hospitals has increased from 60 in 2014/15 to 74 in 2017/18.

Family and public awareness

33. We know from reports received from our clinical teams, that there appears to be a higher awareness and a willingness amongst families to have a conversation about organ donation at the time of death. Repeated waves of our public attitudes survey also report a consistently high level of awareness and understanding of the law amongst the Welsh public.

34. Whilst it cannot be said definitively that these improvements are due to the change in legislation alone, we are very encouraged by the ongoing increases in donor numbers we have seen and by the levels of awareness, and believe the Committee might therefore take a level of assurance from the Welsh experience.

Welsh Government
November 2018