Human Tissue (Scotland) Bill

Bill Number: SP Bill 42
Introduced on: 3 June 2005
Introduced by: Andy Kerr MSP (Executive Bill)
Passed: 2 February 2006
Royal Assent: 16 March 2006

2006 asp 4

Passage of the Bill

The Human Tissue (Scotland) Bill [SP Bill 42] was introduced in the Parliament on 3 June 2005. Stage 1 commenced on 8 September 2005 with the Health Committee as the lead committee. The Stage 1 (general principles) debate took place on 30 November 2005 and the Bill was passed following the Stage 3 parliamentary debate on 2 February 2006.

Purpose and objectives of the Bill

The Bill provides a new framework for organ donation and transplantation, hospital post-mortems, the removal, retention and use of body parts, anatomical examination and the public display of bodies.

The Bill follows on from the work of the Independent Review Group on Retention of Organs at Post-Mortem, which was announced following the interim report of the Bristol Royal Infirmary Inquiry into the retention of organs following post-mortem examinations. The Bill also takes forward a number of the recommendations in the report of the Scottish Transplant Group, ‘An Organ Donation Strategy for Scotland’.

Provisions of the Bill

The Bill repeals and replaces the Human Tissue Act 1961, which governs organ and tissue donation and transplantation from deceased donors, hospital post-mortem examinations, and the removal of organs and tissue for the purposes of audit, research, education and training.

The Bill introduces a new concept of ‘authorisation’ for obtaining permission for organ donation, hospital post-mortem examinations and the removal and retention of body parts at post-mortem for the purposes of audit, research, education and training. This allows an individual adult or mature child (aged 12 and over) to give authorisation for the use of parts of their body after their death. However, if a person’s wishes are not made clear before death the Bill allows the person highest on the nearest relative hierarchy (if an adult) or the person with parental rights and responsibilities (if a mature child) to give...
authorisation. In the event of the death of a child under 12 only the person with parental rights and responsibilities can give authorisation. In the case of a hospital post-mortem an adult or mature child can also nominate a person to act on their behalf following their death. The Bill also makes provision for the use of organs following a procurator fiscal post-mortem, which again is based on the concept of authorisation.

The authorisation process in the Bill for organ donation and transplantation can be referred to as one of ‘opting in’, where an individual takes a positive decision in favour of donating organs and tissue after death for the purposes of transplantation. This is in contrast to an ‘opting out’ or ‘presumed consent’ system where the onus is on the individual to make it known that they are not in favour of organ donation whilst they are alive.

The Bill makes it a criminal offence for medical professionals not to have appropriate authorisation before proceeding with organ donation, hospital post-mortem or the removal of organs and tissue for the purposes of audit, research, education and training. It is important to note that there are different schemes of authorisation for organ donation and transplantation, hospital post-mortem and other parts of the Bill.

The Bill also clarifies the purposes of a post-mortem examination and what parts of the body can be removed and retained at post-mortem for the use of audit, research, education and training. In addition, it repeals the Human Organ Transplants Act 1989, which deals with the transplantation of whole organs from living people and the trafficking of organs for transplantation, replacing it with a new framework for living donation. This carries forward the existing arrangements governing donation of organs and tissue from living donors, but also extend them to cover cases where the donor and recipient are related as well as unrelated. Finally, it amends the Anatomy Act 1984, as respects Scotland, to broaden the definition of ‘anatomical examinations’ and address public concerns about the use of bodies and body parts in public displays.

**Parliamentary consideration**

Much of the parliamentary consideration of the Bill centred round the concept of authorisation and how the different schemes would work in practice. The Committee made a number of legislative and non-legislative recommendations in this regard, many of which were accepted by the Executive, with some leading to successful amendments at stages 2 and 3.

The Health Committee supported the new concept of ‘authorisation’, though was concerned that the different schemes for the various parts of the Bill could lead to confusion. It found merit in the use of specific authorisation forms but also called for a public awareness campaign and appropriate training for professionals. This was accepted by the Executive.

The Committee was particularly concerned that there was an absence of fail-safe mechanisms which would allow individuals to record their wishes,
whether positive or negative, across the range of circumstances dealt with in the Bill. The Executive said this would be covered in guidance and that it was looking at the potential of the electronic health record as a vehicle for recording people’s wishes. There were a number of proposed amendments from individual Committee Members at stage 2, which sought to clarify this, but they were defeated. As part of this debate the Committee sought to have the NHS Organ Donation Register referred to on the face of the Bill to ensure it was clear that it was a suitable method for authorisation as regards organ donation and transplantation, not only for those who were already registered but also for those registering in the future. Whilst the Executive brought forward an amendment, which was subsequently passed, to make it clear that those already registered would be taken to have given authorisation under the terms of the Bill, it did not agree that the Register should be referred to specifically in the Bill as it could potentially be too restrictive and run the risk of implying that other methods of authorisation would be invalid.

The Bill allows for the withdrawal of authorisation. When the Bill was introduced it proposed that should the nearest relative or person with parental rights and responsibilities authorise the use of organs for transplantation then it could be subsequently be withdrawn. The Committee received evidence that there could be serious consequences for the recipient if authorisation was withdrawn at a certain stage in the proceedings. The Committee recommended that this issue be clarified. This led the Executive to lodge amendments at stage 2, which removed the possibility of withdrawing authorisation once given in such circumstances.

The Committee did receive some evidence in favour of the concept of presumed consent for organ donation and transplantation, though was unconvinced of the merits of such a change. Amendments were lodged at stage 2 to introduce such a system but were withdrawn. Amendments were then lodged again at stage 3 but were defeated, though the Executive did note it was not averse to considering a system of presumed consent in the future once the new system had time to become established and evaluated.

As discussed above the Bill creates a new framework for live organ donation. It prohibits living donation from children under 16 years in relation to regenerative tissue. Whilst the Committee accepted this approach it was concerned this could prevent the use of organs involved in a domino transplant. The Executive accepted this and brought forward amendments at stage 2 to ensure that domino transplants (This tends to refer to domino heart and lung transplants where the donor heart and lungs are taken from a patient receiving a complete heart-lung transplant, but because either the heart or lungs are still viable they are used for transplant in another patient) should be possible subject to independent scrutiny.

During the passage of the Bill it became clear that amendments were required to cater for adults with incapacity and live donation. This led to a brief consultation being launched by the Executive, the Committee taking specific evidence on the issue and amendments being lodged at stage 2, all of which were passed by the Committee.
Finally, during stage 1 consideration of the Bill, the Committee received evidence from museum representatives that the new licensing regime proposed for the public display of human remains could put at risk the longstanding arrangements for public access to historical displays in museums. The Executive noted that it had not intended that museums should be covered by the new licensing regime and lodged amendments at stage 2 to make specific provisions for bone fide museums. These amendments were agreed by the Committee.