The Human Transplantation (Wales) Bill

Evidence to the National Assembly for Wales

Health & Social Care Committee

The Kidney Wales Foundation, established in 1967, believes the measures set out in the Human Transplantation (Wales) Bill ( "the Bill") are a progressive proposed change in the law and will be a key component of change in organ donation in the UK. We are supportive of the Bill and provide support of the implementation of the Bill in this evidence to the Health & Social Care Committee of the National Assembly for Wales.

We have been campaigning for the change in the law over many years and we have a determination to see the successful implementation of the law because of the clear effect it will have in changing the cultural approach in Wales and the UK on organ donation and, of course, the lives of so many in the future. It is, however, key that the proposed legislation is implemented with the goodwill of the people of Wales. A transplant law provides only a legal environment which can influence the extent to which potential donors can be used. The law in proper practice, as evidenced by the Bill, will be essential.

Under the current system of informed-consent, the burden of responsibility for the decision is put heavily on the family, and the task of asking for consent is usually delegated to a transplant coordinator. The freedom given by the new law has as a corollary, the fact there may be more responsibility now put on the doctors. Doctors feel responsible for the patient and the patient's family, and are less directly concerned about the needs of the community. This could explain the reluctance of some, in the UK, less so in Wales, to make use of all the possibilities offered by the law in its current form. In stating this we have seen a majority of doctors in favour of the Bill and those against very much in the minority. It illustrates the difficulty of coping with a situation which is new in medical practice. In the UK the British Medical Association has adopted it as policy for a number of years despite repeated failed challenges by its membership. We hope the profession can adapt as a whole. Implemented properly, Wales will lead the way. We believe other parts of the UK, where increasingly the debate is being brought to the surface, will follow. We will then see the real change for patients, who sadly see themselves on a “death row” and “voiceless” as those, with authority provide and offer, in their eyes, despairing solutions of more education instead of real action and the hope of overcoming such a heavy burden of eventual death.

It is heartening to see the majority of politicians and opinion formers and media galvanised to see proper progressive debate and see the need to provide a better life in our society to those who need to be looked after psychologically as well as physically with their families and communities. We appreciate the role of many who have worked diligently in getting us to this Bill stage particularly Government Ministers, Civil Servants, Assembly Members, Assembly Officials and our Supporters.

Roy J Thomas

21 January 2013
Key Points in Summary for Discussion and in Support of the Bill

1. As demand increases year by year for organ transplants, there is a need for new thinking from all Governments and the Welsh Government and the proposed Bill provides a welcome fresh approach.

2. We believe it is important how the policy is worked up with the law and that care is taken in how the Government communicates the messages to the public; as this is where other countries implementing opt out have failed.

3. We support the “duty” placed on Welsh Ministers in Section 2 to promote transplantation. It is often the case that Westminster has not done so as well as Wales and Scotland which is borne out in the numbers of the population on the Organ Donation Register. In recent times First Ministers, Health Ministers and Cabinet Members together with leading politicians across Wales have taken this duty seriously. We pleased to see it enshrined in the law.

4. We support the definition “deemed consent”. It provides clarification and is preferable to presumed consent which can often be misinterpreted.

5. Communication is a complicated subject but the public have shown they are in favour of the proposals although when we polled the public there was over 70% support for an opt out law change some three years ago; and over 63% in a St David’s Day BBC Poll in 2012; but this slipped to 49% in a Poll by Beaufort for the Welsh Government recently.

6. Government needs to communicate the key issues clearly and it does not seem that due weight has been given to our partners such Diabetes UK; British Heart Foundation; British Lung Foundation and WKPA in the Donate Wales Campaign and Opt For Life Cymru - no mention is made in the Explanatory Memorandum of the efforts made by the third sector. This sector is critical to the success of the Bill. A further example is the one important omission from the Communications Strategy, although rightly included in the continuous communication strategy is the role of students in higher education, who contributed so much to the Donate Wales campaign following approaches from the third sector.

7. One of the lessons from the successful implementation of opt out legislation in Belgium in 1986 was the factual dissemination of the issues and the opposition to those we prayed on human fears of death and human organ retrieval. See Appendix A for a summary of the first ten years of the Belgium experience.

8. Lessons should be learnt from the Belgium experience and as an example instead of traditional “road shows” more creative forms of communication could be undertaken such as working with World re-known Gunter Von Hagens’ plastination process “Body Worlds” which brings an element of educational as well as the dramatic and could tell the story of transplantation - see Appendix B setting out the medical success in these fields. The Exhibition is undertaking a World Tour, and is currently in Cape Town, but an approach to the organisers or similar Exhibition describing outcomes of successful transplantation is far more effective than the usual advertising and pamphlets. Personal stories and the effect of transplants on welsh people could feature heavily. The experience of those
waiting and the trauma it causes amongst families is often swept under the carpet, as being too difficult to expose emotionally. The reality of the waiting needs exposure especially on those who have no experience of it and find organ donation or this Bill difficult to support for reasons which they sometimes cannot articulate.

9. A communications plan does not need to be totally led by Government. NHS Blood and Transplant in England have failed to increase the rate on the Organ Donation Register above 30% of the population. Not so in Wales where the BMA indicated in evidence, that the Tell a Loved One campaign led by charities “there has been a 49% increase in deceased organ donors in Welsh hospitals between 2007/08.” NHS BT failed to work with charity partners in England, Wales and N Ireland preferring to work only with Government or select charities it can control. Sadly, the usual communication was a photo shoot with a Patient and a Minister on Queen Street.

10. Accordingly, we believe the Welsh Government at a minimum should work on a new Organ Donation Transplant Strategy based on:

6.1 Implementing new legislation in Wales for “deemed consent” efficiently by working with partners to deliver a substantial increase in donors and not in isolation-it would be a big step for charities to lead such a campaign but governments are not always best placed to bring consensus due to political allegiances and perceived public opinion on trust in messages;

6.2 Delivering a new dedicated transplant infrastructure for Wales and promoting organ donation coordinators and their work;

6.3 Consulting persons of 16 and older in schools and colleges and working with students in Universities and Colleges;

6.4 Promoting the role of the family in discussing organ donation by communication and campaigns and real meaningful discussions with BME Groups and seeking case studies of donor and recipient families in all cases.

11. The existing Organ Donor Register should be improved and efficiencies eliminated and assurances given that NHS BT will accord with wishes of donors with a proper contact with Welsh Government for services otherwise procured properly. NHS BT have always been against this legislation see evidence to the Welsh Select Committee of the House of Commons in January 2012. We certainly hope NHT BT’s views have changed if they operate the new Register.

12. We support the principle of appointed representatives in Section 7 of the Bill but would like to see the promotion of adopted wording for guidance throughout Wales.

13. We support further organs being made available to the rest of the UK as organs have in the past from Europe especially Spain and the UK to Wales.

14. On equality; in our tradition of democracy all rights are balanced by obligations, those in favour of opt out support a framework of law for social obligation. There is a genuine concern about further rational discussion about principles and practicalities of implementation.

We have consulted various multi faith groups who are in favour of these proposals. For example, the Presbyterian Church of Wales has around 28,000 members in some 650 churches as well as strong links with churches abroad.
We have received support from across Wales and in particular Community Councils. We have consulted with all Town and Community Councils in Wales and do so every year.

The Bench of Bishops of the Church in Wales (not the membership) have been opposed to the Bill but their opposition is based on failure to see where the system works in other places and where the Welsh Government has attempted to perfect matters and listen. Time has stood still for the Bench of Bishops as Government consultation after consultation saw improvement and the wishes of individuals respected. Such opposition is unfortunate, as it is built of the sands that State control persists which is unhelpful at best and misrepresents the legislation at worst. It provides alarm where there should be clarity.

15. We believe NHS BT figures should be more transparent and the public need to be more fully aware of the Welsh figures. Since 1 April 2012 in the UK, 494 people have donated organs and 1,279 people have received transplants. 7,494 people are still waiting for transplants. It is apparent in Wales that the numbers are always around the same figure. It is clear that there are in reality more waiting than on the list. In the case of kidney transplants, it is clinically the case, that the future life of an organ transplant for the individual patient is far more successful if a transplant takes place prior to dialysis.

16. Organ Donation and Transplantation offers excellent results for patients. For those with kidney disease renal transplantation provides the most successful and cost effective treatment for established renal failure as supported by the figures and known for some years. However, in Wales a relatively low number of people have received transplants as a consequence of three inter-related factors:

- Lack of availability of organs
- Lack of capacity to undertake transplantation
- Sub-optimal organisational arrangements.

Up to 10,000 people in Wales have renal disease and it affects all age groups. The incidence of renal disease is rising and seems likely to do so for the foreseeable future. The demand for renal transplantation in Wales is projected to continue rising. In terms of provision there is one transplant unit in Wales based at the University Hospital of Wales in Cardiff which serves South Wales. Patients in North Wales receive their transplants in England which is also where all paediatric transplantation takes place (in Bristol).

17. In the early years we pointed to the evidence of Abadie and Gay of Harvard and Chicago Universities (2005) who conducted a study to examine this across 22 countries who have introduced presumed consent systems over a 10 year period. The study found that presumed consent had a positive and sizeable effect on organ donation rates of some 25%-35% higher on average in presumed consent countries. A number of countries have dramatically increased their donation rates following the introduction of soft opt out systems of organ donation. Belgium, for example, which offers a model which can most easily be compared to Wales and the UK, went from 18.9 per million population to 41.3pmp three years after the introduction of opt out legislation. Countries which have introduced “hard” forms of presumed consent have also seen major changes. Austria went from 4.6 pmp to 27.2pmp after five years of presumed consent and Singapore from 4.7pmp to 31.3pmp three years after its introduction. We note further work has been undertaken to support this study and welcome this insight in the Explanatory Memorandum.

18. We have support these proposals as Kidney Wales proposed that the law on consent for organ donation be changed to allow better lives and a change in doing the same thing - that for purposes of disease treatment Welsh residents are deemed to be organ donors on death unless:
- They have opted out.
- They cannot be identified.
- The person’s place of residence cannot be identified.
- The wishes of the deceased can be proven to be contrary after relatives have been contacted.
- Immediate relatives object.

19. The general organisation of transplantation services in Wales is sub-optimal and needs to be improved. In the past NHS Wales has relied on NHS Blood & Transplant (NHSBT) to manage its donor campaigning. NHSBT is based in Bristol with a key role to ensure that donated organs are networked and allocated fairly. NHSBT also manages the National Transplant database and maintains and promotes the National Organ Register. Although the Welsh Government works with NHSBT to identify Welsh specific campaigns Kidney Wales believes that the Donate Wales Campaigns operated with charities were far more successful.

20. Kidney Wales supported the efforts of the Wales Organ Donation Implementation Group (WODIG) who has monitored the implementation in particular of the UK Taskforce recommendations. Following the Clinical Engagement Event in March 2011 Kidney Wales supported the obvious need that all LHBs were asked to revise their specific pledges in respect of donation and transplantation. We agreed that emphasis needed to be placed on the need for each organisation to have an identified Clinical Donation Champion and Donation Committee and to raise awareness, support and commitment to ensure that organ donation should not be an unusual event. However, much more resource is needed and better communication to make this more effective.

21. WODIG states that recruitment is on-going to establish the full team of 266 Donor Transplant Co-ordinations (DTCs) who are employed by NHSBT. We support the fact that 15 embedded specialist nurses for organ donation have been established in Wales and organ donation is included as a module in Year 5 of the medical school curriculum as of September 2011. However despite these developments and objectives, there is a recognition that there is much still to do to increase the number of transplants and further discussion is needed with the voluntary sector.

22. Kidney Wales believes the Welsh Government should consider infrastructure/systems across the world particularly in Europe. For example, Spain, who has the highest donation rates in Europe, has approximately three times as many intensive care beds per million populations as the UK. France who also demonstrates good donation rates of 25.3 pmp have 9.3 Intensive Care beds per 100,000 population (vs. 3.2 in Wales). Wales’ donation rate (2009/10) of 13.7 per million population equated to 41 deceased donations.

23. The example of Spain is often discussed. One failure in comparing Spain is the difference in culture—where donation is expected of the deceased. Spain does not have an Opt Out Register. In 2010 Spain saw a decrease in its deceased donation rates and it is part this has been attributed to a drop in road traffic deaths so again has developed a strategy to increase donation with actions including:

- Earlier referral of possible donors to the transplant co-ordination teams.
- Benchmarking project to identify critical success factors in donation after brain death.
- New family approach and care methods.
- Development of additional training courses aimed at specific groups of professionals supported by their corresponding societies.
- Consensus documents to improve knowledge about safety limits for organ donation to minimise inappropriate discarding of organs.
Use of organs from expanded criteria donors under an ‘old for old’ allocation policy has resulted from adaptation to progressive decline of optimal organs.

National strategic plans to deal better with organ shortage while respecting ethical standards.

In Spain, promotional campaigns and development of particular tools to facilitate discussion have not, as discussed above, been part of the system. Funding is more frontline. The system is based on two basic principles: organisation and continuous adaptation to change. The ‘Spanish Model’ was particularly adopted in Tuscany where the donor rate rose to 40pmp and Croatia and Portugal have also adopted some of the approach with national transplant agencies, network of procurement hospitals and in house figure of medical transplant co-ordinator and both increased the numbers of donors.

24. Implementation of the Organ Donation Taskforce’s Recommendations seeks to improve the donation rates. In 2010/11 Wales saw an increase to 66 deceased donations which equates to 21.9 per million population. If this improvement is to continue, there will need to be adequate Critical Care capacity, (or a viable alternative) in order to continue to facilitate increased donation rates.

25. A limited Critical Care bed stock influences admission policies to intensive care units, and also end-of-life care policies, both of which can potentially influence organ donation rates. We understand from evidence given to WODIG that the ethical tenets of “autonomy, and justice” (fairness) are considerably harder to balance for admission, discharge, donation and withdrawal of care where bed capacity constraints exist. We agree with Critical Care Network in Wales that a successful increase in organ donation will be reliant on adequate resources and capacity to care for and manage potential donors. As highlighted by the Critical Care Network in Wales to WODIG, Wales is already under resourced with the lowest Critical Care bed stock when compared to the rest of the UK and Europe. Spain, the Netherlands, Sweden and France have 8-9 Critical Care beds per 100,000 population, mostly with higher donation rates than Wales. It is therefore recommended that there is an increase in provision of Critical Care beds across the country to bring Wales in line with European neighbours.

26. The Kidney Wales Foundation has for over 46 years, through a thriving fund raising base, supported many aspects of kidney patient care in Wales including transplantation. In addition Kidney Wales played a major role in getting an organ donor card attached to the new driving licence by lobbying 10 Downing Street through the then Welsh Office and was instrumental in setting up Lifeline Wales – a pioneering computer register of people willing to be organ donors in the event of their death. Our current “People Like Us Cymru” patients group aims to demonstrate the need for improved services for kidney patients in Wales and is championed by those patients themselves. The evidence we present is informed by the experiences and views of those in Wales who live with kidney disease and other organ failure every day and our campaigning, support and research.
1. After 2 years of passionate and sometimes emotional discussions, widely publicised, the presumed-consent transplantation law was voted through in the Senate and in the House of Representatives by a large majority from all political parties in Belgium in 1986.

2. The law is obviously accepted by most people and its application is no longer a matter of controversy. Less than 2% of the population have registered an objection to organ donation.

3. After the implementation of the transplant law in 1986, the kidney retrieval rate rose in 1987-1988 by 86% to 37.4 per million population per year. This increase in cadaveric donations was sustained.

4. Until 1986 work with teaching hospitals this had only limited results. After 1986 the number of collaborating hospitals with donor activities increased.

5. The Belgian law obviously provided a legal environment favourable to the collaboration of intensive care units in non-university hospitals. In the absence of a registered will of the deceased, the law leaves considerable freedom to the medical profession. As might be expected, the practical application was variable and the group in Antwerp continued to seek explicit permission of the relatives with the active involvement of a transplant coordinator in contact with the family. It is noteworthy that, after the introduction of the new law, the retrieval rate was unchanged in Antwerp—a strong argument against the hypothesis that the increase in the number of donors was due to the publicity.

6. Confronted with the persistent shortage, Antwerp decided to abandon the strict informed-consent practice. Unexpectedly, a group in Brussels that had until then supported and applied the presumed-consent principle changed to informed consent. Although the contrary is explicitly stated in the legislation, the group felt that the provision of the law granting the family the possibility to oppose donation implied the obligation to ask explicitly for permission. In this centre as in Antwerp, enactment of the law had no influence on the number of organs retrieved. There was no clear difference in attitude between the Flemish and French speaking parts of the country. The determinant factor was the stance of the head of the department. It would, however, be wrong to conclude that families are rushed from the death room without an explanation or that they are confronted with a scar they did not expect on the body of their loved one. As a rule when death is notified, the family is informed of the intention to proceed with organ removal, but explicit permission is seldom asked. This information is usually given by the doctor in charge and not by the transplant coordinator, whose role is often limited to technical and administrative support. No information is given when the family shows total lack of interest or when the relatives cannot be contacted in due time.

7. Since many donors come from non-teaching hospitals, there is a wide variation in attitudes and there are no reliable statistical data on the way in which the given to the family or on the number of cases in which the family made use of its right to oppose donation. The main factor in the positive attitude of the medical profession to the law is without doubt the legal security.

8. The doctors responsible for the donor can decide freely how much information is given, how it is given and to whom, without risk of being sued. In retrospect and in comparison with the earlier situation law has resulted in more openness. Being informed of the intention to proceed with organ removal has proved a less traumatic experience for the family than a request for permission to proceed. The absence of "horror stories" in the media indicates that the medical profession has applied the law in a sensible and humane way.
9. It is clear that, among the countries participating in Eurotransplant, the two with a presumed consent law, Austria and Belgium, outperform in number of donors Germany and the Netherlands, where formal permission of the family is required. One must, however, be cautious in drawing conclusions about cause and effect. The organ retrieval rate is the final result of different factors and events.

10. A transplant law provides only a legal environment which can influence the extent to which potential donors can be used. The number of possible donors is determined by, among other things, the density of the population and its age stratification, the number of traffic accidents, the number of intensive care units and the social security system. The law can obviously only modify the motivation of the medical profession and of the public. Although the differences in overall retrieval rate are impressive, the influence of the type of law on number of donors can still be questioned. More convincing is the fact that the proportion of multiorgan donors is also significantly higher in the setting of a presumed consent law. If we consider the mean values of the last five years within Eurotransplant, it can be calculated from the data in that the mean retrieval rate per million inhabitants in the countries with presumed consent legislation was 65% higher for kidneys, 71% for lungs, 100% for pancreases, 110% for livers and 145% for hearts.

11. Legislation apart, Belgium and the Netherlands have in common a high density of population, a well-developed social security system and a large number of hospitals with adequately functioning intensive care units. In both countries transplantation started early. Some have argued that differences in the number of road accidents explain the differences in organ retrieval. The importance of this factor is not as overwhelming as it seems at first sight, because traffic deaths include people who died “on the spot” and who are, as a rule, not available as organ donors. The potential donors are mortally injured, i.e. those who die within the first days after admission to an intensive care unit. From the 171 road deaths per million population in Belgium in 1992, less than 20 per million population were mortally injured. When the transplantation law was enacted in 1986 the number of mortally injured was 40 pmp; it decreased progressively to 20 pmp in 1992, while the number of organ donors doubled. According to the 1994 Eurotransplant annual report, the cause of donor death was an accident in only 43.7% of the Belgian donors, against 42% for Eurotransplant and 36.9% for the Netherlands. This marginally higher number of accidental deaths among the donors is insufficient to explain the difference in retrieval rate between the two countries.

12. Another interesting point in the comparison between the two countries is the finding that, until 1986, the retrieval rate was nearly identical although informed consent was the rule in the Netherlands and presumed consent was practised in Belgium but not law. This indicates that there is much more in the presumed-consent law than the possibility of retrieving organs without explicit permission from the relatives. Important is the absolute legal security and the official statement that donation is the rule, with some exceptions. The opportunity for the doctors in charge of the donor to decide if, how and to whom the information is given has also been a major factor in the development of decentralised organ retrieval. The importance of this factor is confirmed by experience in Austria; where in 1981 a presumed-consent law was passed, confirming the practice based on the stricter tradition of presumed consent.

REFERENCES
1995:33-9

Appendix B – History of Transplantation of Human Organs and Tissue

Timeline of successful transplants

1905: First successful cornea transplant by Eduard Zirm [Czech Republic]
1954: First successful kidney transplant by J. Hartwell Harrison and Joseph Murray (Boston, U.S.A.)
1967: First successful liver transplant by Thomas Starzl (Denver, U.S.A.)
1967: First successful heart transplant by Christian Barnard (Cape Town, South Africa)
1981: First successful heart/lung transplant by Bruce Reitz (Stanford, U.S.A.)
1983: First successful lung lobe transplant by Joel Cooper (Toronto, Canada)
1984: First successful double organ transplant by Thomas Starzl and Henry T. Bahnson (Pittsburgh, U.S.A.)
1986: First successful double-lung transplant (Ann Harrison) by Joel Cooper (Toronto, Canada)
1997: First successful allogeneic vascularized transplantation of a fresh and perfused human knee joint by Gunther O. Hofmann
1998: First successful live-donor partial pancreas transplant by David Sutherland (Minnesota, U.S.A.)
1998: First successful hand transplant by Dr. Jean-Michel Dubernard (Lyon, France)
1999: First successful Tissue Engineered Bladder transplanted by Anthony Atala (Boston Children's Hospital, U.S.A.)
2005: First successful ovarian transplant by Dr P N Mhatre (wadia hospital Mumbai, India)
2005: First successful partial face transplant (France)
2006: First jaw transplant to combine donor jaw with bone marrow from the patient, by Eric M. Genden Mount Sinai Hospital, New York
2006: First successful human penis transplant [reversed after 15 days due to 44 year old recipient's wife's physiological rejection] (Guangzhou, China) [7] [8]
2008: First successful complete full double arm transplant by Edgar Biemer, Christoph Höhnke and Manfred Stangl (Technical University of Munich, Germany)
2008: First baby born from transplanted ovary by James Randerson
2008: First transplant of a Vertebrate trachea/human windpipe using a patient's own stem cells, by Paolo Macchiarini (Barcelona, Spain)
2008: First successful transplantation of near total area (80%) of face, (including palate, nose, cheeks, and eyelid) by Maria Siemionow (Cleveland, USA)
2010: First full facial transplant, by Dr Joan Pere Barret and team (Hospital Universitari Vall d'Hebron on July 26, 2010 in Barcelona, Spain.)
2011: First double leg transplant, by Dr Cavadas and team (Valencia's Hospital La Fe, Spain)

The first human organ transplant occurred on June 17, 1950, at the Little Company of Mary Hospital in Evergreen Park, Illinois. The suburban Chicago hospital, better known as the "baby hospital" for the high number of births there each year, was an unlikely place for this landmark in medical history. And the doctors who took part in the transplant tried to keep the highly experimental procedure quiet. The subject was a 44-year-old woman who suffered from polycystic kidney disease. She received a donor organ, a kidney, from a cadaver, making the procedure even more controversial.
for the Catholic hospital. (At the time, the church was opposed to the idea that tissue could be taken from a dead person and put into a living person, and that the tissue would then come to life again.) But the three doctors who performed the procedure had the confidence and trust of the sisters running the hospital. Doctors James W. West, Richard H. Lawler, and Raymond P. Murphy were surgeons on the faculty at Loyola's Stritch School of Medicine and the Cook County Hospital but also practiced at Little Company of Mary. The operation was the last resort for the patient, who had seen her mother, sister, and uncle die from the same disease. Word leaked about the operation, and several days after the procedure, when the patient was doing well, the hospital and doctors went public with their breakthrough, making headlines around the world. The transplanted kidney functioned in the patient for about six weeks—enough time for her other kidney to begin working again; she lived another five years before finally succumbing to the disease.

- On December 23, 1954, Harvard University physicians led by surgeon Joseph E. Murray (1919-) performed the world's first successful transplant from a living donor, the patient's identical twin brother. The operation took place at Peter Bent Brigham Hospital (now Brigham and Women's Hospital). Since the patient and the donor had the same genetic makeup, organ rejection was not an issue. The procedure saved the patient's life, and the well-publicized breakthrough immediately opened up the possibility for similar transplants (between identical twins) as well as for the transplantation of other organs. Dr. Murray and other Harvard researchers continued working on the problem of rejection, eventually developing new drugs that reduce the possibility that a recipient would reject an organ from a non-relative. In 1990 Murray was awarded the Nobel prize for his pioneering work. He shared the prize with his friend and colleague E. Donnall Thomas (1920-), an innovator in bone marrow transplant.