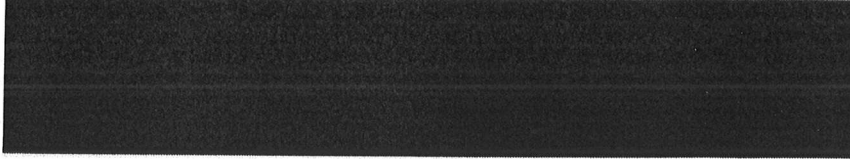


**Health and Social Care Committee
Human Transplantation (Wales) Bill
HT(Ind)34 - Dr Iain J Robbe**

Date: January 9th 2013

From: Dr Iain J Robbé
BSc, MSc (PHM), MSc (MEd, distinction), MB, BS, MRCS, LRCP, MFPHM



Re: Consultation on the Human Transplantation (Wales) Bill 2013

Submission to: National Assembly for Wales Health and Social Care Committee
<HSCCommittee@wales.gov.uk>

Pre-amble

The principles underlying the Bill are deeply flawed for two reasons. Firstly the principle of autonomy is being ignored. It is a lie to claim that deemed consent is a valid form of consent. Deemed consent is a fictitious phrase that ignores international conventions around valid consent.

Secondly the principle of involving families/persons in a qualifying relationship in a soft opt-out system is being ignored. It is a lie to claim that the system in the Bill will involve families because families will have no right to veto donation which is a core issue in a soft opt-out system.

Section 2: to promote transplantation

36% of the Welsh population are on the Organ Donation Register (McGlade, 2011) and an extensive study of more than 46,000 UK hospital deaths found that 59% of families will agree to the removal of organs and tissues from potential donors (Barber, 2006).

Furthermore the rate of deceased organ donations per million population is higher in Wales than in the rest of Scotland and Northern Ireland and in some recent years the rate has been higher than England (McGlade, 2011). Crucially, overall in the UK the donation rates are increasing (European Union, 2007, Organ Donation Taskforce, 2011, Organ Donation Taskforce, 2012). International comparisons have identified a range of factors that influence donation rates including introducing systems of opt-in, prompted choice, mandated choice and opt-out (Barber, 2006, European Union, 2007, McGlade, 2011, Wellesley, 2011). Other influences include altering the organisation and infrastructure of the existing transplant system particularly the approaches to relatives, taking decisions about different priorities for investment in health care, and running campaigns to influence underlying public attitudes and awareness (Nuffield Council on Bioethics, 2011, Organ Donation Taskforce, 2008, Rithalia, 2009, Simpkin, 2009).

The weight of evidence supports improving the opt-in system (National Institute for Health and Clinical Excellence, 2011). Instead of moving to an opt-out system the Welsh Assembly Government should have made a policy decision to improve the opt-in system based on sound ethical principles, respecting Human Rights, and showing consistency with the expertise of the UK Organ Donation Taskforce (Organ Donation Taskforce, 2008).

Sections 3 to 8: authorisation of transplantation activities and consent

Deemed consent and presumed consent (Erin, 1999) are equally fictitious phrases and the Welsh Assembly Government has no right to presume it can disregard an individual's autonomy, ignore the law surrounding valid consent, and take an individual's organs and tissues without express consent.

The safeguard that families/people in qualifying relationships could provide information that the deceased did not consent is meaningless when the deemed consent process is spurious. Also, clinical staff under pressure from managers will be able to ignore the families' information and wishes by citing the law created by the Welsh Assembly Government. In the Bill there is no right by a person in a qualifying relationship to veto donation which is a core issue in a soft opt-out system (Nuffield Council on Bioethics, 2011).

Barriers to implementation and unintended consequences of the Act

Barrier to implementation from fear of breaching Human Rights legislation: patients admitted to hospital expect doctors and other health care staff to respect the ethical principles of autonomy and beneficence. Also, the European Convention on Human Rights, Article 8, states that everyone has the right to respect for their private life so taking their organs and tissues without explicit consent would breach that Human Right.

Barrier to implementation from errors in identifying that a person has opted-out: even in an organisation as committed to helping people as the NHS, mistakes can occur, for example, prescribing errors including the wrong drug, wrong dose and wrong patient (Dornan, 2009), and wrong patient and wrong site errors for procedures carried out by physician and surgeons (Stahel, 2010). Telephoning the duty officer at the NHS Blood and Transplant service (Explanatory Memorandum paragraph 185) is highly inadequate for exchanging such important information. It is therefore likely that although a person has opted-out, a mistake would be made and their body would be used for the removal of "any relevant material" (Bill section 3). Consequently there would be legal claims for compensation and criminal prosecutions of clinicians and other health care staff.

Unintended consequence due to adverse publicity arising from removing organs and other materials from a person who had opted-out: it would have a significant detrimental effect on the willingness of any Welsh resident to donate voluntarily before death e.g. blood, platelets, bone marrow, as well as after death with a huge increase in people opting-out as has happened in other countries following this type of error (Wellesley, 2011).

Unintended consequence amongst the public: the use of deemed consent is highly likely to provoke anxiety and fear amongst individuals and their families about admission to hospital and perceptions that their organs will be “taken” (Monaghan, 2012) would lead to feelings of resentment. Overall a reduction in voluntary donations through informed, expressed consent is likely to occur.

Unintended consequence amongst health care professionals: hospital staff under pressure from management will face psychological trauma through taking brain stem deceased patients for organ removal surgery without the support of the patients’ families (Dominic Bell, 2012).

Unintended consequence through changes in patient care: it might be the intention that there will be no official changes in the way patients are cared for, the ways in which death is confirmed, or the clinical decision making about transplants.

However there are no guarantees that changes will not occur in the new culture of deemed consent and not respecting the views of the family of a deceased person. Welsh residents would be viewed on admission to hospital as both patients and deemed consenters as providers of organs and tissues, clinical teams would experience pressures to give less consideration to the patient’s wishes and the families’ wishes and more consideration to the need for organs and tissues. There could be improved access to intensive care facilities enabling more admissions of brain stem dead or cardiovascular dead patients whose organs and tissues could be removed.

Conclusion

If the Bill is enacted then it will represent a costly and dangerous experiment by the Welsh Assembly Government using Welsh residents as the subjects in that experiment.

The policy is deeply flawed in ethical terms and in terms of the weaknesses of the evidence to support it.

There is a high risk that the current progress in donation rates will be halted or reversed due to resentment against unethical government interference, failure to obtain informed consent, ignoring the wishes of families/people in qualifying relationships, and forcing health care professionals to consider people under their care as both patients and potential sources of organs.

Wales might be able to rely on donations of blood, organs, and other relevant materials from genuine donors in England, Scotland and Northern Ireland but there will be delays and supply problems and it will be poor compensation for the damage that will have been caused.

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