

Mr Mark Drakeford,
Chair of the Health Committee,
The National Assembly for Wales.

17th January 2013.

Dear Mr Drakeford,

Re: Explanatory Memorandum for the Human Transplantation (Wales) Bill.

I would like to bring to your attention a crucially important factual error in the memorandum, as well as other important points in the Memorandum that the Welsh Government needs to address.

1. The factual error occurs in Clause 102, in the section entitled “Evidence Base to Establish Impact of Proposed Legislation”. It states “For example, an opt-out system is operated in Spain and it has the highest donation rate in the world with approximately 32 deceased donors per million of population”. *Spain does not operate a presumed consent system.* The Director of the Spanish Organ Donation Organisation (Organizacion Nacional de Trasplantes www.ont.es), Dr Rafael Matesanz, is on the public record several times making this point, most recently in an article published in the British Medical Journal on the 30th October 2010 (volume 341, pages 922-924). The authors of this article, listed on the last page, are myself, Paul Murphy (an intensive care physician), and Rafael Matesanz. I attach a copy of this article. If you read the middle column of the first page you will see “Crucially, Spain does not have an opt-out register for those who do not wish to become organ donors. Not a penny is spent on recording objections to organ donation by Spanish citizens, nor on public awareness of the 1979 legislation. Clearly, the presumed consent law in Spain is dormant, and it pre-dates key policy changes made in 1989. In these circumstances, Spain’s outstanding deceased organ donor rate cannot reasonably be attributed to its presumed consent laws”.

If you have any doubt on this point, you should contact Dr Matesanz on [REDACTED] or [REDACTED]. Linking this factual error, about Spain and presumed consent, with the true fact that Spain has the best deceased donation rate in the world, in a section on the evidence base for the proposed legislation, is clearly and quite outrageously misleading. Any expert adviser will know that Spain does not operate a presumed consent system.

The Welsh Government must issue to Assembly Members and the Public a corrective statement along the lines of “The Welsh Government regrets that the statement in Clause 102 of the Explanatory Memorandum for the Human Transplantation (Wales) Bill is incorrect. Spain does not operate a presumed consent system, as stated in Clause 102, although it does have the highest rate of deceased organ donation in the world. Spain’s 1979 presumed consent legislation predates the key policy changes made in 1989. Spain does not have, and never has had, an opt-out register or other means of registering objections to organ donation by Spanish citizens. Spain does not spend any resources whatsoever to publicise the 1979 legislation”. It would be a scandal if the Bill were passed by Assembly Members given a manifestly misleading statement by the Government of Wales.

If the Welsh Government believes that the mere presence of the legislation in Spain somehow subliminally influences donation, then it should emulate Spain and pass the legislation but without a donor register and without spending resources on publicity.

2. There is an additional point that will also mislead Assembly Members and the public. It concerns the 2006 study by Abadie and Gay, comparing organ donation rates in countries with and without presumed consent systems. This is prominently quoted in Clause 21 and Clause 103 as the basis for expecting a 25% to 30% increase in donation rates after the introduction of presumed consent. As correctly explained in Clause 104, the Abadie and Gay study was one of 4 methodologically sound “between country” comparisons identified in a review of the literature on presumed consent by the University of York. This review was commissioned by the Department of Health’s Organ Donation Taskforce. The University of York also identified 5 methodologically sound “before and after” studies, comparing donation rates before and after the introduction of presumed consent legislation.

However, even with the best methodology, the quality of the conclusions is entirely dependent on the quality of the data analysed. The study by Abadie and Gay made a critical error, which should have been noted by the Welsh Government – it included Spain as a presumed consent (opt-out) country. It is worth noting that another of the 4 between country studies identified by the University of York, that by Gimbel et al published in 2003, correctly classified Spain as an opt-in country. This error in the Abadie and Gay would inevitably bias its findings in favour of presumed consent, and therefore invalidate its conclusions.

The Explanatory Memorandum is also selective in its quoting of the University of York’s report. The University of York’s negative comments are omitted. For example, in paragraph 1 of page 28, the University of York states regarding the Abadie and Gay study that “Countries were selected from an initial panel of 36, with some being excluded because of low transplantation rates, many of which were presumed consent countries. Thus it is possible that the impact of the presumed consent law was overestimated”.

The Welsh Government appears not to have asked itself why the Department of Health’s Taskforce found against presumed consent in November 2008. This Taskforce is known to consist of a large group of knowledgeable specialists in many fields. In January 2008, prior to its November 2008 report on presumed consent, this same Taskforce made another report which has led to the spectacular increase in deceased organ donation in the UK, as noted in the Memorandum. After stagnating or falling since a peak in 1989/1990, the deceased organ donation rate in the UK has risen from 809 donors in 2008 year-on-year to 900, 959, 1010 and 1088, and is on schedule for another big increase in the year to April 2013, probably to ~1150. The credentials of this Taskforce are excellent.

Going through the details of the 4 “between country” studies and the 5 “before and after” studies is tedious for non-specialist audiences. However methodologically sound these papers might be, they are poor quality papers, some extremely poor, and hardly a basis for policy. I mentioned above the Gimbel et al study, and that it had correctly assigned Spain as an opt-in country. However, oddly, it excluded Spain from the analysis, as an outlier. The University of York states on page 28 “If Spain had been included, the magnitude of the impact of presumed consent would have been lower”. There were 2 other between country papers. The paper by Healy et al, published in 2005, analysed 17 of 30 OECD countries. The University of York comments on this paper (page 29) “As with Abadie et al, it is not clear whether the choice of countries may have affected the results of this study. There was no rationale provided”. In any case, the results of Healy et al were not statistically significant. The last

paper, by Neto et al, was published in 2007. The University of York had concerns about the statistical analyses, which are outside my expertise.

The 5 “before and after” studies all involved 3 countries - Singapore, Austria and Belgium. One of these concerned secondary legislation in Singapore for liver donation, and is not directly relevant. The other 4 were brief, 1 to 2 page meeting reports, rather than full-length, peer-reviewed papers, and they were published more than 20 years ago. At the time, Austria and Singapore were using hard presumed consent. In all 3 countries, numerous additional initiatives were introduced with the legislation, and it is impossible to ascribe any role to the presumed consent legislation.

Perhaps the Welsh Assembly should organise a public, expert discussion of these papers.

3. Other points.

a. The presumed consent legislation fundamentally aims to move the decision about donation from the family to the hypothetical wishes of the donor. It is claimed that this will better accord with the potential donor’s wishes. However, failure to register an objection on an opt-out register, ie the absence of an objection, is hardly the best way to ascertain a person’s wishes. It defies common sense to say so. *There is in fact no good way of ascertaining the wishes of a potential donor who has neither opted in nor opted out, or discussed the issue with family.* If establishing the wishes of the potential donor was paramount in the mind of the Welsh Government, an opt-out register without presumed consent legislation would achieve it as effectively as with legislation, at a much lower cost. It is worth remembering that in Spain, which has the world’s highest deceased donation rate, and more importantly for the current discussion, the world’s lowest refusal rate (currently only 10%), the decision about donation rests with the potential donor’s family (see BMJ article).

b. The bureaucratic intimidation described in clause 44 is unnecessary.

c. I do not think that 50% or 60% support for contentious legislation that will affect the rights of all the citizens of Wales is nearly enough to proceed.

d. The Memorandum states that there is no alternative to presumed consent legislation. That is a remarkable comment for the Welsh Government to make. One alternative, now that transplant coordination is being developed so effectively following the January 2008 Taskforce recommendations, is to aim for an acceptance rate of 90% over the next 5 years, as has been achieved in Spain. Not by presumed consent legislation, but as the Spanish have done, by excellent public relations and public education (see BMJ article), which should be possible in Wales.

e. I think it is worth noting that if we look around the world today, we see that Spain and the USA have excellent deceased organ donation rates without presumed consent. Spain has an outstanding acceptance rate, without presumed consent. By contrast, Sweden, which operates a presumed consent system, has a donation rate substantially lower than the UK’s. The case for presumed consent is weak, and it will be costly. The money can be spent much more effectively to achieve the improvement in donation rates which it is our duty to achieve.

Yours sincerely,

Professor John Fabre
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