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Llywodraeth Cymru
Welsh Government

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Professor Mark Drakeford AC AM
Cadeirydd - Chair

Y Pwyllgor Iechyd a Gofal Cymdeithasol
Health and Social Care Committee

Cynulliad Cenedlaethol Cymru
National Assembly for Wales

28 February 2013

Dear Mark

Human Transplantation (Wales) Bill

Thank you for your letter of 22 February regarding the information I agreed to provide to the Committee.

I deal with each of your points in turn at Annex 1. You also asked for my view on the issue of potential donor referral and whether this could deliver additional donors if the current "gaps" were closed. I have also addressed this point in Annex 1, together with a number of other points which were discussed at Committee and which I feel would benefit from further clarification.

A handwritten signature in black ink that reads "Lesley Griffiths". The signature is written in a cursive, flowing style.

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Annex 1

Human Transplantation (Wales) Bill: further points following Committee meeting of 20 February 2013

1. Assessments made in determining £2.9 million over 10 years for communications strategy, including the information used from the banning smoking in public places campaign; finally, what £50,000 may be able to buy in terms of the longer term communications work

From 2013/14 until 2020/21, a budget of £2,984,000 has been allocated for communications. As you will see from the Explanatory Memorandum, the majority of the budget is focussed on the years up to and including the opt-out system becoming operational. The rationale is to focus on the communications needed in the two years leading up to the start of the opt-out system to ensure the population of Wales knows the choices available to them.

The comparisons I made at Committee to the communication strategy for the implementation of the ban on smoking in public places were intended only to illustrate the high levels of awareness and message penetration achieved by the communications work delivered by the Welsh Government. The budget used for the public information campaign for the smoking legislation was approximately £1.318 million in the year prior to implementation. The ban came into force in April 2007. We achieved a 98 per cent awareness rate.

In comparison, the Human Transplantation (Wales) Bill proposes an even greater budget. We propose to spend £318,000 in the year of Royal Assent (for planning assumptions, this coming financial year), increasing to £808,000 next year prior to implementation and £1.453 million in 2015. The figure for 2015/16 allows a budget for direct mailing to all households in Wales immediately prior to the introduction of the new system.

Awareness Levels

In terms of success, a similar phased communications approach was deployed for the ban on smoking in public places. Research undertaken to evaluate the effectiveness of the communications campaign showed 98 per cent of the general public and 100 per cent of businesses in Wales were aware of the legislation in May 2007.

We have deliberately phased the introduction of an opt-out system to allow a two year communication exercise to ensure the population of Wales is aware of the new law and the choices available to them. The length of time available to undertake a wide range of communications is much longer than was available for the ban on smoking in public places. The additional time allows for the key messages to be delivered and provides the opportunity for regular monitoring of public awareness levels between 2013 and 2016. This will in turn allow for the assessment of the effectiveness of the communications work. Communications can then be adapted as necessary, ensuring messages are targeted and reaching everyone on a timely basis.

Ongoing communications, post implementation

Longer term, a current indicative budget of £100,000 will be used to follow up the successful two-year communications campaign. This will be primarily used for targeted communications to those people who may be new to Wales or approaching the age of 18.

As the communications campaign progresses, it will be regularly reviewed and plans can then be adapted to ensure that the ongoing communications are sufficient. The budget has been based on our best assessment of the communications requirements. Activities are still being considered for the post implementation period of 2016/17 and beyond, however this may include:

- Contacting patients on the approach of their 18th year;
- Targeted work for students;
- Work to target people moving into Wales as well as new registrants to Welsh GPs.

In summary, £50,000 has been budgeted for the notification of 17 years olds and a further £50,000 for general communications, including poster/leaflet production and targeted distribution through above routes.

Low cost/free opportunities to be investigated

Other free communication opportunities will be investigated such as partnerships with local authorities and information on organ donation included in regular mailings such as council tax statements. The Committee may wish to note that initial discussions have taken place with the electoral commission and the inclusion of additional information unrelated to elections or the electoral register may not be included in regular mailings to citizens. Working with Welsh Universities, there may also be long term free opportunities by including information through UCAS for students when applying to universities in Wales. Discussions will take place with the Department for Education and Skills on distributing information through Personal Health and Social Education or equivalent lessons to young people at GCSE ages.

2. Cost of the recent Heart to Heart road show events held from January to February this year

The total cost of the roadshow which ran over from January 25th to February 14th and visited over 28 locations was £19,524. This can be broken down into the following categories:

- Branding and transport of the Ad Van: £4,730 (excl VAT)
- PR support including staffing and travel etc: £12,980 (excl VAT)
- Promotional items (t-shirts for staff, stickers and postcards) £1,814 (excl VAT)

Based on a conservative estimate, the team spoke to over 5,000 members of public during this time and there was an overwhelmingly positive attitude towards organ donation and a higher than expected levels of awareness for the proposed legislation. The Committee may wish to note that during the roadshow the team were only approached six times by individuals who disagreed vocally with the legislation. It also gained widespread media coverage.

3. What is considered to be the requisite level of public understanding of when a person's consent will be deemed in order to achieve satisfactory compliance with Human Rights legislation, including any precedents or comparisons with other international systems.

I am content that the National Assembly for Wales has the legislative competence pursuant to Part 4 of the Government of Wales Act 2006, to make provision in an Act relating to how consent is to be given in Wales to the removal, storage and use of human organs and tissues for the purpose of transplantation.

The Presiding Officer has also decided in accordance with section 110 of the Government of Wales Act 2006 that the Bill is within the legislative competence of the Assembly.

The purpose of the Human Transplantation (Wales) Bill is to change the way in which consent is to be given to organ and tissue donation in Wales, for the purposes of transplantation. The Bill provides that, in the absence of express provision in relation to consent, consent will be deemed to have been given in most cases. This means that, after death, a person's consent will be deemed to have been given unless they had expressed a wish for or against donation. However, deemed consent does not apply to the under 18s, people who have not lived in Wales for at least 6 months before they died, and people who lack capacity to understand that consent could be deemed in the absence of express action being taken.

In addition, in practice people who cannot be identified or whose next of kin cannot be found will not be included in the deemed consent system.

The Bill therefore creates a default position which provides that consent is deemed to be given but individuals may expressly opt out if they object (or expressly opt-in if they wish to make a positive expression of their decision to consent to donation). However, deemed consent can be overturned where information is provided by a relative or friend of long standing evidencing that the deceased would not have consented to their organs and tissues being donated for the purpose of transplantation. This is what is often referred to as a "soft opt-out system" for organ and tissue donation.

European Convention on Human Rights (ECHR) considerations

A provision of a Bill will be outside the legislative competence of the Assembly if it is incompatible with Convention Rights or European law.

In a deemed consent system individuals need to be fully aware of the need to consent or object to an action and be fully aware of the consequences. This underlines the need for public education.

Articles 8 and 9 of the ECHR provide a right to respect for a private and family life and to freedom of thought, conscience and religion. These are qualified rights which require a balance between the rights of the individual and the needs of the wider community. In weighing such a balance, proportionality requires that a measured and justifiable approach is undertaken.

As part of the requirements inherent in articles 8 and 9 there was a need for widespread consultation before introducing legislation and this has been done. There is also a need for a sufficient period of adjustment after the legislation is made to allow it to gain public consensus and bed in. That is why there is a two year period after the legislation is made and before the new system goes live when a significant awareness raising campaign will be undertaken.

Although partly general in its application (promoting transplantation as a means of improving health), section 2 of the Bill also contains an important specific duty on Welsh Ministers relating to educating those resident in Wales (and potentially those likely to become resident) about the circumstances in which consent can be deemed.

The two year communication campaign will ensure those subject to the deemed consent system are aware of the new legislation and the choices available to them. Two years has been set aside for communications on this Bill to ensure that all sectors of society are reached including specific work with harder to reach parts of the community. As I indicated above, the smoking ban communications attained a reach of 98 per cent of the Welsh population evidenced through tracking survey work. Two years is a significantly longer period of time than was available in relation to the smoking ban and reflects the need to communicate the key messages and to assure compatibility with Convention rights. Arrangements will be put in place to track public awareness.

It is recognised that particular ECHR considerations arise in relation to some groups of people and so certain categories of people including those who lack capacity, children, and those whose identity is unknown, will not be subject to the deemed consent system.

Several countries, including Spain, Austria, and Belgium, have opted for a change in legislation and introduced presumed consent. A recent review of European case law has not identified any cases where deemed/presumed consent legislation (and/or practice) has been challenged either on grounds of interference with article 8 or article 9 rights or otherwise.

I am progressing the Bill in such a way to ensure compliance with the Convention including adequate safeguards in respect of consent choices available, family involvement to ensure wishes and beliefs are respected and appropriate arrangements in respect of vulnerable adults and children.

4. Qualifying relations

Discussions took place in Committee about the “ranking” of the relationships listed at section 17 of the Bill. I think it would be helpful to clarify further the purpose of this list because I want to ensure there is a clear understanding of the policy intention.

My previous letter explained the difference between the people who are *required to make a decision* in express consent cases, which stays the same as now, with a hierarchy of close family members (i.e. a ranked system) – as opposed to the people who *may provide information* about whether the deceased person would have objected to their consent being given in deemed consent cases.

At the heart of our deemed consent system is the need to safeguard the wishes of the deceased. This is achieved by making it as easy as possible for information to be provided which may indicate the deceased person would not have consented. In the Bill we have chosen to facilitate this by having an unranked list for deemed consent which sets out the friends and family who could provide information.

The reasoning behind having an unranked list in deemed consent cases is very clear – it is in the interest of the deceased person because we cannot know who people may speak to about their views on organ donation. Therefore I considered it desirable to have a wider list rather than a narrower one. In light of ECHR considerations, a deemed consent system should allow adequate opportunity for information to be provided to show the deceased

would not have consented. In practice, friends and family will be able to provide information if they have it.

One point of discussion at Committee was on the role of clinicians in interpreting these lists. I believe there are sufficient safeguards in the existing clinical guidelines to protect the interests of clinicians for actions which they take in good faith and we can reinforce these in the Code of Practice.

In summary, the policy intention is to introduce an important additional safeguard in relation to deemed consent. The consequences of ranking the list will be to afford less opportunity to explore whether the deceased would have objected.

5. Potential for negative impact on organ donation as a result of requirement for coroner consent

As I set out in my letter of 14 February 2013, and at Committee, the Bill makes no changes regarding the role of the Coroner – section 13 of the Bill on Coroners replicates the effect of section 11 of the Human Tissue Act 2004. In some cases, if the person's death is sudden and of unknown cause, or unnatural, traumatic or violent, it may come under the jurisdiction of the Coroner and so donation, or steps to preserve organs for the purposes of donation, cannot go ahead without his or her agreement. This is as now.

The current Human Tissue Authority Code of Practice 2 – Donation of Solid Organs for Transplantation – contains guidelines for what should happen where a person dies suddenly and uncontrolled non-heart beating donation is a possibility. Consulting the Coroner about such cases is already an established part of the process and the question of delay because of the Coroner is not an issue since the requirements of the Coroner must be satisfied first. The current law, as well as the new one, allows clinicians to take the minimum steps necessary (subject to the Coroner's consent where required) to preserve organs, using the least invasive procedure, whilst the question of consent is established.

I gather the concern from members is interventions to preserve organs could be performed on a person and then the Coroner could stop them, meaning the interventions were performed unnecessarily. The HTA guidelines make clear that the Coroner must be informed and advised at the point the potential donor is identified. The specialist nurse liaises with the Coroner's officials on all these matters. If a Coroner requires a post mortem, then this decision will be communicated quickly and perfusion and organ donation would not then be allowed to proceed. However, the Coroner may exercise discretion in favour of permitting perfusion subject to further investigations. It is perhaps possible for perfusion to be ceased in light of those further investigations, however, that is what happens now and our proposed legislation does not change this process.

6. Novel forms of transplantation

I indicated to the Committee that I was prepared to bring forward a Government amendment to include a specific power of Direction for the Welsh Ministers. The power will mean Welsh Ministers, after consultation, can give directions to NHS Blood and Transplant on which organs and tissues will not be included in the deemed consent system. My intention will be to exclude from the deemed consent arrangements so-called "composite tissue" donations such as face and limb.

7. Prisoners

I have also reflected on the points made in Committee about prisoners, and the view they should be excluded from deemed consent because they are not living in Wales through choice. Whilst I understand the point being made, I do not propose to amend the Bill for the simple reason that it is not possible to define and seek to exclude certain categories of person in the way suggested. The issue becomes complex if exceptions are to be considered – for example, would length of sentence have to be considered; other persons may be detained under other circumstances such as secure mental health facilities, or indeed other scenarios we have not yet envisaged of people being in Wales through no choice of their own. I believe the most straightforward answer is to retain the concept of “ordinarily resident” which together with the conversation with the family will allow cases to be considered individually. To make an exception here may have unintended consequences on other policies. I believe the overriding principle should be to make those who reside in Wales, whether in prison or not, subject to Welsh laws. In addition, prisoners should be afforded the same choices in relation to organ donation as the rest of the population.

8. Potential for closing the “gaps” in the current system

I noted the line of questioning followed by the Committee during Mr Phil Walton's evidence in relation to the referral rates, with the inference being that if we could close the current gap on referrals we may deliver around 8 additional donors in Wales each year.

It is not of course the case that once a potential donor has been identified, that this will result in a donation. Last year there were 250 potential donors in Wales, resulting in 67 actual donors. Taking potential donors through to the point of becoming actual donors involves a complex set of decisions and actions, including identification and referral of the patient; neurological death testing in DBD cases; approach to families and final consent to donation. There is a fall-off rate at each of these stages, thereby reducing the number of donors going forward. These are the areas which the Organ Donation Task Force work sought to address. We have always said an opt-out system is part of a wider series of actions to address these range of factors and we are working with NHSBT on a new UK strategy which will seek to further address some of these issues.

There have been improvements in the referral rates over recent years and with even better identification and referral of patients we could well see an increase in the number of families approached. This is of course desirable and backed up in best practice guidelines issued by the National Institute for Clinical Excellence. However, the single largest significant change will come from improving the consent rate from the current 65 per cent. Our continued view is until we tackle the issues around the consent rate, we are unlikely to see further significant gains. Opt-out systems help to clarify wishes and give relatives greater reassurance the wishes of their loved ones are being followed.

9. Other issues

Critical care

We have received a report from the Critical Care Network and it is currently being considered. I will share any information with you as soon as possible.

Evaluation strategy

This is being prepared and I will provide you with an overview by the end of April.

Code of Practice

My officials are in discussion with the Human Tissue Authority about the drafting of the Code and its contents, including whether there should be any further reference to diagnosis of death and DCD cases; the issues raised about nominated representatives and what should happen when there is more than one and they do not agree. I can confirm it is my intention the Committee will be provided with a draft code before Stage 3.