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Llywodraeth Cymru
Welsh Government

Eich cyf/Your ref
Ein cyf/Our ref LF/LG/0089/13

Mark Drakeford AM
Chair
Health and Social Care Committee
National Assembly for Wales

14 February 2013

Dear Mark,

Human Transplantation (Wales) Bill: emerging issues

Thank you for your letter of 5 February setting out a number of issues and questions arising from the evidence you have been gathering on the Human Transplantation (Wales) Bill.

I deal with each of your points in turn at Annex 1. There is one key point I wish to emphasise. The international evidence continues to make an association between improved rates of consent and countries which have introduced an opt-out system. I aspire for Wales to be amongst these best performing countries, on a sustainable basis.

The evidence you have taken highlights the complexity and the variety of issues and opinions which are involved with organ donation. What gives me confidence is the success others continue to have. With vision and determination all these issues have practical solutions. The core principle is simple: improving our consent system to help save and improve lives. I note with interest the announcement from Northern Ireland that they will also be consulting on a soft opt-out system for consent to deceased organ donation.

I look forward to attending Committee again on 20 February for my final evidence session.

Regards

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Annex 1

Human Transplantation (Wales) Bill: response on some of the emerging issues

1. Practical difficulties in determining whether consent can be deemed to have been given, and whether this could lead to fewer donors

The international evidence does not support this. It rather indicates the exact opposite. Countries with opt-out systems are associated with higher rates of donation. In Wales we will have a two-year communication campaign which will highlight the subject of organ donation and encourage discussion within families. Unlike now, people will be able to register a clear yes or no to donation. Where they do neither, it will be in the knowledge their consent will be deemed; but qualifying relations can provide information about whether the deceased would have objected. I believe this will provide a framework for greater clarity of individual wishes, which in turn will provide comfort to families who will be much clearer about their loved one's wishes

I agree the new arrangements will of course result in some change in practice in terms of the consent process. We are working with NHS Blood and Transplant and the Human Tissue Authority on the practicalities of adapting the current consent process in order to deal with the requirements of the new legislation. The existing questionnaire for donor families already contains a number of substantive questions, and I do not believe the new system will add to this significantly. In most cases, questions about residency and mental capacity will be straightforward to determine as part of the process.

The type of questions asked of families, even today, may seem intrusive and unnecessary to those of us not involved in the organ donation process. However, the skill and training of the Specialist Nurses means they are approached sensitively and with care. I believe the requirements of the new system can be carefully woven into the conversation and will not cause significant difficulty for staff or families. Other countries manage it well and so can we.

2. Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD)

You have asked for an explanation of the terms DBD and DCD and how the Bill applies in relation to them.

Donation after Brain Death (DBD) may take place where death is confirmed following neurological tests to establish whether the patient has any remaining brain function. Patients declared brain dead may have suffered head trauma, for example in a car accident, or a massive stroke. These patients are sometimes also called "heart-beating donors" because the circulatory system is maintained through a ventilator whilst consent is established and until the donation takes place.

Donation after Circulatory Death (DCD) may take place following diagnosis of death by cardio-respiratory criteria. These patients are called "non heart-beating donors" because death follows the cessation of the body's cardio-respiratory functions. DCD may be either "controlled" which describes organ retrieval which follows the planned limitation or withdrawal of treatment at the end of a critical illness from which the person will not recover; or "uncontrolled" which occurs following a sudden, irreversible cardiac arrest. Uncontrolled DCD is rare in the UK at present.

In either DBD or DCD, it is important to separate decisions about the care and treatment of the patient from decisions about organ donation and you have heard evidence in Committee to that effect. The provision in the Bill and the introduction of a system of deemed consent do not alter this in any way. The Bill, as in the current Human Tissue Act, makes it lawful to take steps to preserve part of a body for potential transplantation, including in those situations where it is still being established if a decision on consent has been or will be made. Having a system of deemed consent does not somehow make it “easier” to retrieve organs or exert undue influence over decisions around the care and treatment of a patient. It merely indicates the deceased individual may have had no objection to the idea of organ donation and informs the conversation with family members which may then ensue.

The Bill deals with consent to donation and does not alter *any* current practice in terms of the diagnosis of death. I am aware of Professor Harpwood’s evidence to the Committee but, with respect, I do not agree that we should define these terms in the legislation. There is no current statutory definition of death/deceased person, but rather a duty exists in the Human Tissue Act 2004 and as amended by our Bill to empower the HTA to issue guidance on the matter. There have also been a number of documents issued by the Academy of Royal Colleges and the UK Donation Ethics Committee to guide medical and ethical practice in this area, providing the necessary consistency across the UK. Whilst I appreciate Professor Harpwood’s view that we could start with a clean slate in Wales and choose to define these matters, I do not think this is something which we should be seeking to include in our legislation.

However, in light of both Professor Harpwood and Sally Johnson’s comments, officials are reviewing the use of the word “deceased” in section 12 of the Bill in the context of taking steps for preservation for transplantation.

3. Registration of wishes

Under the new arrangements, people will have a choice to either register a wish to be a donor (opt in); register a wish not to be a donor (opt out) or do nothing, in which case their consent may be deemed to have been given. The register will not record people whose consent will be deemed.

Our policy preference is for a single UK register which will contain any recorded wish because this is the solution which poses least risk when it comes to identification. We are in discussion with the other UK Health Departments about whether we should use this opportunity of a change in the law in Wales to redevelop the existing Organ Donor register (ODR) for the whole of the UK. This would future-proof the register, and is the most cost effective proposal. We have received positive responses from all the UK Governments and will be setting up an all-country meeting shortly. One of the key issues is to ensure a decision to opt out taken by a Welsh resident is available to clinicians in other parts of the UK, since any recorded decision of the deceased will have to be taken into account under the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006. Having a single register for the whole of the UK, capable of showing these details, will resolve this situation.

In terms of people who have currently opted-in to the ODR in Wales, our intention is they will be contacted and asked to confirm their decision in light of the new legislation. It would certainly be possible for someone to remove themselves from the opt-in register and choose to be classified as having their consent deemed. However, I think this unlikely to happen in most cases, since I can think of no advantage to doing so. We will be encouraging people who have already made a formal decision to be a donor to keep that decision on record. It is of course possible for someone to change their recorded opt-in wish to an opt-out wish

but the intention of doing so by large numbers of people is not supported by the results of our public attitudes survey.

4. Appointed representatives (section 7)

The ability to appoint a representative to make the decision about organ donation is something which exists under the existing Human Tissue Act 2004 and which will continue under our new legislation. Even now, there exists a small risk of the appointed representative not being present at the time donation is discussed, and other family members being unaware of the appointment. Under the current law, it is possible that family members would be asked to take the decision about donation if no-one knew about the existence of an appointed representative.

Under the new system, I understand concerns have been raised in Committee that in a situation as described above, where the appointed representative is not known about, the person's consent could then go on to be deemed. We intend to allow for further clarification and safeguards of the deceased's wishes by providing for the recording of the appointed representative on the register, something which does not happen now.

However, it could be possible for an appointment to be made either orally, or in writing, and for the person not to have recorded the appointment on the register. Therefore, the communications campaign will encourage people who decide to appoint a representative to tell other family members about their decision.

Where more than one representative has been appointed, only one of them needs to give consent, unless the terms of the appointment state they must act jointly. This is in line with guidance set out in the current Human Tissue Authority Code of Practice.

5. Coroners (section 13)

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 the person's death may come under the jurisdiction of the Coroner and so donation cannot go ahead without his or her agreement. This could include the steps necessary to preserve part of a body for transplantation as I have mentioned above. The Bill does not change the timescales involved in this process and hospitals will already have local arrangements in place with their Coroner, which I expect to continue.

6. Codes of Practice (section 14)

I intend to make available to the Committee a briefing on the likely content of the Code of Practice in time for Stage 3. We will continue to liaise with the HTA about the overall timescales for the actual draft Code as well as its content, and seek to accelerate this if possible.

7. Relevant material (section 16)

It is our clear policy intention that deemed consent will not apply to so-called "novel" forms of transplantation. The types of transplant being discussed (i.e. hand, face) are known as composite tissue transplants and even under the current system, they are dealt with differently. Current practice, which has been endorsed by the Human Tissue Authority, is to require the express consent of family members even if the deceased person is on the ODR.

However, I understand the concerns being raised and I am currently considering this issue.

8. Interpretation (section 17)

I am aware there has been discussion in Committee about the ranking of relationships, how disagreements between families will be resolved, etc. and some confusion about the lists and why one is ranked and the other is not. Briefly, the difference in the list is predicated on the actions being required of the qualifying relations, as I will explain below. Effectively there are two lists of qualifying relationships in the Bill, each with the same people on them, each there for different purposes.

The first *unranked* list exists for the purposes of deemed consent. Any person on the list at section 17(2) may provide information as to whether the deceased may have objected to their consent being deemed. The reason this list is not ranked is because those people are not being asked to make a *decision* on donation, but rather to provide *information*. This is because the deceased has already made a decision to have their consent deemed and the law will recognise this as a valid consent, unless a person on that list can say otherwise. In practice, this does not mean every person on the list has to be contacted; clearly that would be unworkable. However, it provides the opportunity for those people present to say whether they know or think anyone else might know, if the deceased would have objected. As indicated above, in practical terms this will be worked into the conversation so as to encourage the people present to think about the question and whether anyone else should be contacted and asked if they have any information. This is an important additional safeguard in relation to deemed consent: ranking the list would reduce the opportunity to say whether the deceased would have objected.

The second *ranked* list only applies to people who do not fall within the deemed consent arrangements, i.e. excepted adults and children. For these deceased individuals, if they have not expressed a wish themselves, the decision on donation passes to the person at the top of the hierarchy of qualifying relationships. The list is ranked because when a decision is called for, it would be impossible to give everyone on the list equal ranking as this would run the risk of no decision ever being taken. Therefore, in relation to express consent, we are not changing the current system and have retained the ranked relationships as provided for in the Human Tissue Act 2004.

It is not the case that an objection by someone in a qualifying relationship would be enough to prevent donation taking place. As happens now, disagreements amongst family members have to be carefully handled with emphasis being placed on open and sensitive discussions. The focus should be on the deceased person's wishes wherever possible, but healthcare professionals are not there to traumatise family members by insisting on donation. Each case has to be dealt with individually and in accordance with best practice which will be set out in the Code.

I have covered your query about the definition of death/deceased under answer number 2 above.

9. Costs

You have asked for my observations on evidence put to the Committee that we have not taken account of costs to the NHS in Wales in removing organs for donation which are then used in transplants elsewhere in the UK. The Explanatory Notes contains a very thorough financial impact assessment on the legislation and show the financial benefits an increased number of donated organs could bring, including an analysis based on an assumption that only 30% of the organs are used in Wales.

I do appreciate the point which is being made however. The allocation and use of organs has always been done on a UK-wide basis and for very good reason this will continue under our new soft opt-out system. The cross border nature of the transplantation programme means it is not always a simple matter to directly attribute costs and savings to particular organisations – there is nothing particularly new in that – however the NHS in the UK and society as a whole benefits. I do not dismiss the point being made, but I feel these are relatively minor considerations in the overall scheme of things, and can detract from the wider aim of the legislation.