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British Medical Association Cymru / Wales

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Introduction

BMA Cymru Wales is pleased to provide evidence to Health and Social Care Committees inquiry into the general principles of the Human Transplantation (Wales) Bill.

The British Medical Association represents doctors from all branches of medicine all over the UK. It has a total membership of almost 150,000 including more than 3,000 members overseas and over 19,000 medical student members.

The BMA is the largest voluntary professional association of doctors in the UK, who speak for doctors at home and abroad. It is also an independent trade union. BMA Cymru Wales represents some 7,000 members in Wales from every branch of the medical profession.

Overview

The BMA is delighted that the Welsh Assembly Government is showing strong leadership on this issue within the UK and is moving ahead with an opt-out system for organ donation in Wales. You may be aware that the BMA has been campaigning for an opt-out system for organ donation for many years. We are delighted that Wales is leading on this important change.

We are very pleased that the default position under the Bill, if people choose not to make their views known, will be to save lives. Over time this will lead to a change in philosophy within society so that donation becomes seen as the usual thing to do. As stated in our response to the consultation on the draft Bill, however, our preferred model is a standard form of soft opt-out as practised in other countries, rather than the combined opt-in/opt-out system proposed in the Bill. We have some concerns that introducing this 'hybrid' system carries some risks, of:

- making the system too complicated leading to confusion or misunderstanding
- making the already complex task of informing the public about the changes even more difficult
- leading to uncertainty among the family about the individual's wishes and
- ultimately, reducing some of the anticipated benefits.

We recognise that this may be an interim measure, in order to address the complications caused by other parts of the UK retaining an opt-in system, with a view to the whole of the UK moving to a full opt-out system in the future. If this is the case, this should be made clear as other parts of the UK will be closely monitoring the success of the Wales system as part of their own policy development.

If the system is adopted, as presently described – in either the short or the long term – it will need to be very carefully monitored. We support the Welsh Government's commitment to undertake research to identify areas that are both successful and also those that are less successful. Despite these concerns, we believe that, with proper and careful implementation, it will be a significant improvement on the current system.

In addition, the BMA:

- believes that opt-out should apply to those over 16 rather than 18
- questions the benefit of allowing people to nominate someone to make decisions after their death under an opt-out system;
- is unclear about the rationale for removing the possibility of consent from someone in a qualifying relationship if a nominated individual is unable to give consent
- believes the Bill should refer to the period during which the individual has had capacity, since the new system was in force, rather than how long they have lacked capacity and
- would wish to see a Regulation making power in the Bill to exclude certain forms of transplantation from the deemed consent provisions – such as face and limb transplants.

Section 2 – Duty to promote transplantation

The way an opt-out system is implemented is crucial to its ethical acceptability. Key to this is that information about the new system, and how it will affect individuals, must be available to all people who will be affected by it. We are very pleased, therefore to see this duty to inform the public specifically included in the Bill. We also welcome the detailed consideration that has been given to how this will be achieved in practice (as set out in the explanatory memorandum).

Section 4: Consent: adults

Opt-in/opt-out

The consent model chosen by the Welsh Government differs from the model suggested by the BMA in its evidence to the consultation exercise. The Welsh system gives the individual more options to choose from - opt in, opt out, nominate a spokesperson to make the decision and also the essential change of principle which deems consent in the absence of any recorded decision. The BMA has concerns, however, that this is a complicated model that risks causing confusion for individuals. Conveying the range of options, and the differences between them, will add to the complexity of the message to be conveyed.

Nominated individuals

A standard opt-out system would not include provision for nominated individuals and it is unclear why this has been included. The BMA is also concerned that where an individual has nominated someone to make the decision, and that person cannot be contacted, nobody else can give consent. This is a change from the current situation (under the Human Tissue Act 2004) and the rationale for this change is unclear. The Human Tissue Authority's code of practice says at para 108: '[t]he nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practicable to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship.' Not allowing anyone else to consent, if the nominated individual is unable to do so, increases the chance of organs being lost unnecessarily. For example, if a man nominated his wife to make decisions and both were involved in a road traffic accident such that she was unable to communicate his wish, the organs could not be used; even if other family members knew that he wished to donate, the Bill, as currently drafted, would prevent this from happening. If there is to be a system for nominating individuals to make decisions, the process should mimic that under the Human Tissue Act.

It is also unclear how, in practice, information about the fact that someone has appointed a nominated individual would become known to the treating team. Is there to be provision on the register for this? Or, is the onus on the individual to ensure, during his or her lifetime that this information is known to relevant people (such as the GP or family members) who can then inform the treating team? Given that a failure to recognise that the individual had nominated an individual would result in consent being deemed, it must be clear whose responsibility it is to establish whether someone has nominated an individual to make decisions.

Section 5: Consent: excepted adults

The Bill includes as 'excepted adults' individuals who have lacked capacity for 'a significant period before dying' the BMA feels that the length of time they have lacked capacity is irrelevant. The relevant issue is whether they have *had* capacity for a reasonable period of time since the new system was implemented and therefore had the opportunity to opt out if they wished to do so. If it would be helpful to quantify this, rather than rely on subjective assessments of a 'reasonable period', it could be set at 6 months, in order to be consistent with the residency requirement and the period given to people approaching their 18th birthdays. An individual who dies 10 years after the new system came into force may have lacked capacity for nine years but in the first year, knew about the system and wanted to donate, therefore did not opt out. In our view this should be sufficient for consent to be deemed. Therefore, the definition of excepted adult should refer to the period for which they have had capacity, since the new system came into effect, rather than the period for which they have lacked capacity.

Section 6: Consent: children

The BMA believes that the opt-out system should apply at the age of 16, given that this is the age at which young people are legally deemed to be competent to make their own decisions. At 16, there is a presumption that young people can make all kinds of very important and complex decisions regarding their care and treatment including the decision to opt-in to organ donation. The BMA can see no reason for setting a different age for young people to opt-out of organ donation than for other important decisions.

Additional comments

Relationship between this Bill and the Human Tissue Act 2004

It is unclear why some parts of the Human Tissue Act relating to transplantation have been repeated in the Bill and others have not. For example, clause 12 of the Bill repeats the provisions for preservation for transplantation in the 2004 Act but the provisions in the 2004 Act concerning provision for living organ donation are not repeated in the Bill. Thus the consent provision for living donation is included in the Bill but not the safeguard of requiring Human Tissue Authority approval of all cases. The explanatory notes makes clear (at para 8) that this safeguard will still apply (under the 2004 Act) but for the avoidance of doubt, this should be made explicit.

New forms of transplantation

It is unclear whether the new system would apply to new forms of transplantation such as face or limb transplants. In the BMA's view express consent should continue to be required for such procedures for the foreseeable future, and a Regulation making power should be included in the Bill to exclude such forms of donation. Para 20 of the explanatory memorandum explains that such transplants are currently excluded from the current opt-in arrangements but does not state the situation regarding the Bill. Even if, in practice, new forms of donation would not be subject to deemed consent, there would be benefit in formalising this within the Bill for the avoidance of doubt. It would be unfortunate if, following a news story about face or hand transplants, a number of people opted out of donation erroneously believing their face or limbs could be used on the basis of deemed consent.

Further information on the BMAs position

Please find enclosed, for your information, a copy of the BMAs response to the Welsh Governments previous consultation which outlines further many of the points above.