HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM BRITISH MEDICAL ASSOCIATION

Key strengths of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known

The BMA is a strong supporter of a ‘soft’ opt-out system for organ donation, where there continues to be a role for the family, and we have been campaigning for this since 1999. Our support is based on the following points:

- We believe that, as one part of a broader strategy, a shift to an opt-out system will have a positive effect on donation rates.
- Studies show strong support for organ donation amongst the public, but only just over half of the Scottish population has registered on the organ donor register. An opt-out system will help to overcome this disparity and make it easier for those who are willing to donate - but never get around to signing up to the register - to have their wishes respected.
- We support the principle behind an opt-out system – that if people do not object to their organs being used after death, those organs should be available to save lives.
- Under an opt-out system individuals have exactly the same choice as in an opt-in system – to donate or not to donate. The decision not to opt out of donation is as much of a ‘gift’ as a decision to opt in.
- Under an opt-out system, organ donation becomes the default position which, with public support, changes cultural expectations in society. This creates a more positive view of organ donation which is very likely to reduce the significant number of families who object to donation when approached.

We wish to highlight the following strengths of the specific proposals put forward in the Human Tissue (Authorisation) (Scotland) Bill.

- **Chapter 2** – We are pleased to see that the deemed consent provision applies to ‘adults’ who are defined in the Human Tissue (Scotland) Act as someone who is 16 years or over, rather than restricting it to those aged 18 and over, as in Wales. This is because, at 16, we believe it is reasonable to assume those covered will have seen the publicity about the new system, be able to fully understand the implications of it for them as an individual and act on it by opting out if that is their wish.

We are also in agreement that those aged 12 and over should continue to be able to give express consent for, or opt out of, donation after their death and that these declarations carry the same weight as the decisions made by adults.
• **Section 6, para 6A (4)(b)(ii)** – The provision to allow families to provide evidence that despite giving express consent for donation, the individual would not want donation to proceed in the circumstances that have arisen. The example given in the explanatory notes is of someone with beliefs that would only regard someone as ‘dead’ when their heart ceases to function and so may not be willing to donate in circumstances where death is diagnosed using neurological criteria. This reflects the focus throughout the Bill on the wishes of the deceased individual which we fully support. It may also encourage some people who would otherwise opt out to sign up for donation in the knowledge that their views will be respected.

• **Section 6 para 6C (4) and other similar clauses** – The inclusion of provision to permit donation if evidence is provided that, despite opting out, the individual’s most recent view was that he or she was willing to donate organs after death. Given that our focus is on facilitating the wishes of the individual, this is a sensible approach which caters for someone who registers a view on the organ donor register but then changes their mind and does not get around to changing it. It also makes clear that the reason the donation is proceeding or not proceeding is because of the views of the individual, not simply those of the relatives. Guidance, however, will be needed for the health professionals involved about what type, and strength, of evidence would be needed.

• **Section 7(2) para 6D(5)** – Provision to make regulations to exclude particular parts of the body from deemed consent. This allows deemed consent to be limited to the more common organs and tissues that people would expect to be included. This is important so that if there is media publicity about developments in face transplants, for example, people do not opt out for fear that their consent to face donation might be deemed.

• **Section 8 para 6E (2) and other similar clauses** - These clauses provide welcome confirmation that the fact that an individual has not signed up to the organ donor register should not be interpreted as an unwillingness to donate. This reflects the fact that many people are happy to donate organs after their death but simply never get around to making their views known.

• **Section 12 (2) para 1B**– It is helpful that express authorisation for donation by a child continues to be valid once the child becomes an adult and there is no obligation to seek to renew the authorisation.

• **Section 16 para 10A** – We are pleased that there are provisions to extend those who can provide authorisation for donation on behalf of a child beyond those with parental responsibility. We also support the repeal of the current provision that excludes local authorities with parental responsibility from providing authorisation.

Through public awareness campaigns, and with more information being provided in schools, young people will increasingly have thought about, and voiced opinions on, organ donation, even if they have not gone so far as to register a wish to donate on
the organ donor register. As a general principle, and as far as possible, steps should be taken to facilitate those wishes.

For this reason we can see no reason for the absolute prohibition on allowing local authorities, with parental responsibility, to authorise donation. As with all other cases, legal authorisation does not mean that donation must proceed and it will be a matter for the specialist team to assess the situation and decide whether donation is appropriate. If, for example, the young person had discussed donation with those providing care and it was known that he or she was keen to donate organs after death, the local authority should be able to provide authorisation.

For similar reasons, we can see no reason why an older sibling (16+), grandparent or other close relative could not provide the required authorisation to permit donation to proceed if the parents are not available (if, for example, the child and parents were all in a car accident and the parents did not have capacity at the time authorisation was needed).

- Chapter 6 – The duty to inquire provides reassurance that the register will be checked for express consent or an opt-out and that the family and relevant others will be consulted to identify any unregistered objection to donation. While this is what we would expect to happen in practice, it is helpful to make this a requirement on the face of the Act. This explicit requirement to make inquiries also accords with the principle, underpinning the Bill, that it is the individual’s latest wish that should determine whether donation proceeds.

**Key weaknesses of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known**

We wish to highlight the following weaknesses of the specific proposals put forward in the Human Tissue (Authorisation) (Scotland) Bill.

- **Section 6 para 6B(3) –** We are very keen to ensure that it is as easy as possible for people to opt out of donation if that is their wish. It is unclear why an opt-out declaration must be made in writing or made to the register organisation orally or in writing. The explanatory notes state that, in practice, people will not be able to opt out through other means such as the DVLA, passport office or GP. We would prefer to see as many ways as possible for people to opt out, recognising that these mechanisms need to feed into a single database to avoid the risk of different decisions being held in different places.

- **Section 7 para 6D (3) -** The provision stating that an adult is incapable of understanding the nature and consequences of deemed consent (and therefore is not deemed to have consented) if they lacked capacity for ‘a significant period ending immediately before the relevant time’. In our view, it should be the period of time the individual has had capacity since the legislation came into force (or they reached the
age of 16), rather than the amount of time they lacked capacity before death, that is the relevant factor.

Consider a man who is 20 when the legislation comes into force and wants to donate, so is happy for his consent to be deemed. He loses capacity at the age of 40 – as a result of an accident – and dies 2 years later. If it is the amount of time he lacked capacity that was relevant, consent would not be deemed but it is highly questionable whether that would reflect his wishes, given the amount of time he had to opt out if that had been his wish.

It has been suggested by some (including in the debate in Wales) that a prior decision cannot be relied upon because the individual might have chosen to opt out during their period of incapacity. This is meaningless because, by definition, individuals who lack capacity cannot make and communicate decisions. It is also unclear why the same argument is not made in respect of those who have opted in to donation, where subsequent incapacity is considered irrelevant.

Key strengths of the plans for authorisation of pre-death procedures

We welcome the provisions in chapter 5 to clarify the lawfulness of certain pre-death procedures aimed at facilitating donation or increasing the likely success of the transplantation.

Our view has always been that where authorisation has been provided for donation, this includes authorisation for some tests that are required or desirable to facilitate that process but which are not part of the patient’s standard medical care, provided that, in each case, they are minimally invasive and are not harmful to, or risky for, the patient. The justification for intervening in these cases is threefold:

- it benefits patients to facilitate their wish to donate organs;
- their authorisation (or decision not to opt out) can be seen to incorporate authorisation for the necessary steps to fulfil that objective and to make the donation as successful as possible; and
- provided there is no harm to the patient and considerable benefit to others (ie the potential recipients) such action is justified.

It is helpful to have clarity about the legal status of carrying out such procedures and to have a clear process to follow.

We note that consideration is being given to expanding the information provided to those who are considering their views on organ donation about the type of tests that might be required to facilitate donation. We welcome such a move but care needs to be taken to ensure that the information is short and to the point so that people are not deterred by the sheer volume of information to read.

Key weaknesses of the plans for authorisation of pre-death procedures
Our understanding is that, in some circumstances, this chapter will introduce a legal requirement for express consent/authorisation for the pre-death procedure itself (ie in addition to the authorisation for donation), where previously this was not required (including during the transitional period where consent for donation will be deemed once the legislation comes into force). If this is a correct interpretation of these sections, we would expect to see a strategy in place to ensure that those likely to carry out such procedures are aware of the new rules so that they do not inadvertently break the law. There is currently no mention of the steps that will be taken to inform health care teams about this change.

Other comments

- It is not clear how this Bill fits with the Human Transplantation (Wales) Act 2013 and with forthcoming legislation in England. If an adult has lived in Scotland for more than 12 months, and has not opted out – such that his consent would deemed if he died in Scotland – what would happen if he died in Wales? Or in England once the opt-out legislation is in place there? Is there a way of linking the pieces of legislation such that an adult who lived in Scotland but died in Wales could be deemed to have consented? This would reflect the focus on facilitating the individual’s wish that underpins the Bill.

- We welcome the comments in the policy memorandum about the importance of evaluation and monitoring the new system but note that there is no statutory provision for this in the Bill itself.

- It is essential that there is a continuing campaign of public information both before and after the change is introduced so that there is widespread public awareness and to stimulate discussions within families and between friends.