HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM THE GENERAL MEDICAL COUNCIL

Thank you for the opportunity to respond to this call for evidence. As you will know, the General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK.

- We decide which doctors are qualified to work here and we oversee UK medical education and training
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers
- We take action to prevent a doctor from putting the safety of patients, or the public’s confidence in doctors, at risk.

While regulation of the medical profession is reserved to Westminster, the GMC operates within the legal and legislative structures of the different jurisdictions within the UK. As an example of this, our guidance for doctors reflects the laws of all Scotland, and when a law changes we seek senior counsel’s advice on whether we would need to update our guidance.

We would be happy to answer any questions on the points set out below.

Question 1 – What do you think are the key strengths and weaknesses of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known?

The GMC does not take a position on what an appropriate system for authorisation for tissue or organ donation from the deceased should be. Our comments are therefore restricted to requests for clarifications on various provisions in the bill.

Advance wishes

We note that health workers will have a legal duty (16H(2)(a)) to ‘take reasonable steps to inquire into whether there is in force

- i an express authorisation by the adult
- ii an opt-out declaration by the adult’
We note that a person could either register their express authorisation (opt-in) or their opt-out on the Organ Donor Register or, in an alternative written form. For opting-in, an alternative written form will include (but is not necessarily limited to) a donor card. We note that explicit authorisation allows a donor to exclude certain tissues and organs from being donated.

If the patient did not register their advance wishes (either to opt-out or to opt-in) on the Organ Donor Register, it would be helpful to provide clarification on the types of steps that might be expected of health workers to make, as part of their duty to enquire. This includes whether or not these steps might depend on particular circumstances (for example, if the window of opportunity to donate is particularly tight).

**Duties of health workers**

In the absence of an opt-in or opt-out declaration by a patient, we also note that health workers will have a duty to enquire into whether the adult ‘is an adult who is incapable of understanding the nature and consequences of deemed authorisation’. The bill also states that ‘an adult is incapable of understanding the nature and consequences of deemed authorisation if, over a significant period ending immediately before the relevant time, the person was incapable of understanding’ what is involved in the deemed authorisation scheme.

We think it would be useful to have clarification on what steps might reasonably be expected of health workers in relation to making these inquiries?

Further, where doubt has been raised with regards a patient’s possible incapacity (at the relevant time), it is important to note that the health worker would not be carrying out the capacity assessment themselves – but making a judgement based on reports from others, such as family and/or friends.

It is also important to note that the starting point of any assessment is a ‘presumption of capacity’ and where doubt has been raised about capacity, this is judged on a ‘per decision’ basis. In other words, capacity is not an all or nothing concept and a person might have capacity in some areas, but not others.

Therefore, in the present context, unless a specific capacity assessment had been made in relation to the patients understanding of the deemed authorisation system, the judgement made by the health worker could be based on assumptions about their ability to understand given the patient’s former situation at the relevant time. These assumptions might be reasonable in some situations (e.g. the patient had advanced dementia) – but might be less straightforward in others.
Question 2 – What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?

Interface with the Adults with Incapacity (Scotland) Act 2000

We think it would be useful to have clarification on the interface between these provisions and the Adults with Incapacity (Scotland) Act 2000. For example, where pre-death procedures involve continuing treatment on a patient that is of no benefit to them, this could be seen as conflicting with the requirement that the principle of ‘benefit’ must be given effect when making decisions on behalf of a person with incapacity. This has the potential to cause confusion for healthcare professionals and those close to a patient.

It will therefore be vital that all parties are aware of the legal framework that applies to authorisation of pre-death procedures and in particular, to ensure that it aligns to patient expectations about what authorising donation means in practice.

Question 3 – Do you have any other comments to make on the Bill?

We understand that there might be certain types of tissue or organ (such as ovarian or testicular tissue) that might never be eligible for donation without the explicit written consent of the donor him or herself. We would advise that in carrying out their roles, health workers would benefit from being explicitly aware of what these exemptions are.