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Legal framework governing deceased organ donation in the UK

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Editor's key points

- UK law is based significantly on the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006.
- Current initiatives regarding consent in the UK revolve around decisions to opt-out and mandated choice.
- Where the patient lacks decision-making capacity, all aspects of the patient's best interests must be considered.

Summary. Laws and policies governing the use of organs for transplantation are evolving rapidly in response to sensitivity to ethical concerns and increasing shortages of transplantable organs. They are necessarily becoming increasingly detailed and complex. Professional practice will be enhanced by clear statements of current provisions, and the debates accompanying their formulation and evolution. This is necessarily a highly selective contribution, with focus on what are perceived to be the most critical items affecting contemporary deceased donation, apart from the meaning of death itself.

Keywords: consent, informed consent; presumed consent; mandated choice; ethics; jurisprudence; organ donation; public opinion; tissue and organ procurement

It has been perceived, by clinicians and lawyers, to be necessary to have a clear and supportive legal framework governing organ transplantation, especially in the light of the general uncertainty regarding legitimate activities involving the corpse. These laws should ideally be clear and facilitative, rather than an impediment to adequate levels of organ donation, while at the same time ensuring appropriate levels of public trust.

There are inevitable tensions between the interests of donors, potential transplant recipients, and transplant and other healthcare professionals, which make law making in this sphere perennially controversial. Notably, and generating particular challenges, with respect to living organ donation, the procedure is not principally intended as a therapeutic intervention for the donor. In respect of deceased donation, the handling and treatment of the living patient at the end of their life will itself influence the possibilities for organ donation after death. The need for such care of a patient to be seen as an end in itself generates inevitable unease for some carers that the needs of others will inappropriately influence and dictate a person's end-of-life care.

The above considerations are all without regard to the nature of such organ donation laws themselves and how they impact on organ donation rates, including the long running debate between proponents of explicit and presumed consent.

The legal background

In the UK, the legal provisions governing the medical and scientific uses of the dead human body have largely emanated from statute law. These date back to the Human Tissue Act 1961 as regards organ transplantation, and the Corneal Grafting Act 1952 for corneal transplantation. These early statutes governed the removal and use of tissue and organs taken from deceased bodies. Current legislation now governs the removal, storage, and use of corpses and parts of corpses for transplantation. These legal sources now vary across the UK after devolution, with the Human Tissue Act 2004 applicable to England, Wales, and Northern Ireland and the Human Tissue (Scotland) 2006 applicable to Scotland. They both came into effect in September 2006.

The above acts followed the organ and tissue retention controversies of the late 1990s and the early part of this new millennium. The practices revealed by the Bristol Royal Infirmary and Alder Hey Childrens' Hospital Inquiries in particular highlighted the inadequacy of existing post-mortem retention practices in terms of paternalism, absences of information, and failures of communication. However, they also revealed an apparent need to move to an explicit statement of consent embedded in law for the legitimate retention and use of human material for research after death.[1] While explicit consent had always been obtained in clinical practice from relatives of organ donors, regardless of the actual terms of 1961 Act, this was by no means routinely the case in the research/pathology sphere.

> '*Where the deceased has refused consent before death - . . . organ donation may not legitimately take place. Where the deceased consented . . . removal and donation can legitimately take place, but there is nothing to* oblige *clinicians to take and use the organs*'

The 2004 Act is a comprehensive piece of legislation applicable to many uses and to material taken from the living and

the dead. The Scottish legislation applies only to material taken from deceased persons, with the exception of some specific offences applied to the removal of material from the living. Thus, the latter is not a holistic legislative framework in the same way as the 2004 Act, although many of the other frameworks and processes in that act are also applied in Scotland as a result of agreement with the Scottish Executive, that is, by way of the Human Tissue Authority.

In contrast, the law governing medical treatment of the living, in general, is governed by an amalgam of common law and statutory rules. In England and Wales, the Mental Capacity Act 2005 is the central piece of legislation in this sphere, and in Scotland, the Adults with Incapacity (Scotland) Act 2000 is pivotal. With regard to organ donation, the law in this area is especially relevant to the end-of-life care of potential deceased organ donors, relating to the condition of potentially transplantable organs, and in particular regarding warm ischaemia time. These rules are discussed further below.

Consent

Consent for organ donation can be written or oral, and may be given by the deceased before his/her death or by a third party, usually a close relative or friend. In the UK, there is no requirement that the 'appropriate consent' for removal of organs and their use for transplantation be in writing provided it has been made explicit in some way. In Scotland, it is explicitly stated that the 'authorization'—as it is termed there—must be given either in writing or orally. This may be by way of inclusion of the person's name on the NHS Organ Donor Register or the signing of an organ donor card, or direct communication with healthcare staff or relatives. Where the deceased has made a decision to refuse consent or authorization before death, this is binding on clinicians and organ donation may not legitimately take place. Where the deceased consented or authorized donation, then no-one is legally empowered to override this, so that removal and donation can legitimately take place without more being required, but there is nothing to *oblige* clinicians to take and use the organs in this situation, for example, where relatives object.

Farsides' contribution in this issue focuses on ethical as opposed to legal issues relating to donation.[2] It also includes discussion of consent, and in particular usefully considers what information ought to be made available to potential organ donors. Some further practical information regarding consent is to be found in the article by Vincent and Logan.[3]

The general policy underpinning the 2004 Act, and even more so the 2006 Act in Scotland, is that the wishes of the deceased person should hold sway in such circumstances. Apart from in Scotland, if the deceased person had not made any decision relating to consent during their lifetime, there is power to appoint a nominated representative to make the decision instead.[4] In the absence of such a representative having been appointed, and in Scotland in any event, the decision falls to be made by a 'qualifying relative' (nearest relative in Scotland) in the highest class of hierarchically listed relative available.[5] Only the consent of one person in such a class is required by law, but once more, there is no obligation to proceed in such an eventuality.

> *'In England donation to a specific individual may be permitted where donation is not made conditional on such a request'*

Minors are empowered to make decisions for themselves, if they possess decision-making capacity, otherwise the decision is made by a person who had parental responsibility at the time of death (or in lieu of such a person, someone in a qualifying relationship).[6] In Scotland, a child over the age of 12 may give an authorization in writing for organ donation after death. In the absence of such an authorization, consent may be given by someone with parental rights and responsibilities, who may also do so with respect to a child under 12.[7]

Consent may not be conditional with regard to any particular individual or group/class of recipient, but in England, donation to a specific individual friend or relative may be exceptionally permitted where donation is not made conditional on such a request and other pre-requisites are satisfied.[8]

While coroners have no actual power to provide consent or authorization for the removal and use of organs for transplantation, where the death is required to be reported to the coroner, it will not be possible to proceed further with donation without the prior permission of the coroner.

Opting out

There is a whole array of different organ donation laws around the world, with a spectrum from explicit consent at the one end to so-called 'presumed consent', or opt-out laws at the other. These latter laws permit donation where there is no evidence of any objection from the deceased person before their death, but vary markedly in terms of whether relatives have an ultimate right of veto and the information that must be provided to relatives after the deceased's death. The latter, dubbed 'weak' opting-out laws, are in the majority and exist in nations such as Belgium. It is this model which has been favoured by the British Medical Association and is intended for adoption in Wales. A systematic review of comparative laws and 'before-and-after' national effects of law reforms conducted by the Centre for Reviews and Dissemination at the University of York for the Organ Donation Taskforce on opting-out laws concluded that:

> *'The between country comparison studies overall point to presumed consent law being associated with increased organ donation rates (even when other factors are accounted for) though it cannot be inferred from this that the introduction of presumed consent legislation* per se *leads to an increase in donation rates. The before and after studies suggest an increase in donation rates following the introduction of presumed consent legislation, however it is not possible to rule out the influence of other factors on donation rates.'*[9]