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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]

The review concluded that opt-out laws alone are unlikely to explain the difference in donation rates between jurisdictions, although such laws were 'associated with' increased organ donation rates. A distinct causal relationship could never be realistically established even controlling for other variables. Moreover, there is no doubt that increased rates of donation may be achievable through other means, such as the Collaborative Breakthrough Initiatives in the USA, which attempt to ensure best practice through systems redesign. Indeed, it is alleged by many that Spain's very high donation rates (the highest in Europe by some way) are a product of the infrastructure and systems approach developed there, rather than the effect of its presumed consent law.

It is difficult to be definite about the effect of opt-out laws on donation rates as they operate as a backdrop to discussions with families, which differ in their content across individual regions, and may highlight a general cultural attitude at a society level. Thus, when commentators argue that, as most presumed consent laws accord the final word to the family, there is no real difference with explicit consent laws anyhow, there is a danger of over-generalization. In addition, in presumed consent systems, relatives do not have to authorize donation, only fail to declare an objection to it, which may be psychologically easier at a time of stress and grief.

'A failure to object [to presumed consent] is no kind of consent at all'

It is not the effect on donation rates alone that reflect the acceptability or otherwise of a presumed consent law. It has to be recognized that in many jurisdictions, there is an absence of any proper mechanism for recording objections from the (pre)deceased and/or for soliciting objections from relatives, so there is little pretence that the system is grounded in any form of consent whatsoever. In many such systems, objections are easily and routinely recorded though (e.g. in a register), such as in Belgium. Many commentators contend that a failure to object is no kind of consent at all. It is perhaps possible to argue though that where supposed levels of willingness to donate within the society are high, presumed consent laws likely reflect the willingness of the deceased to donate more accurately, or at least no less accurately, than under a system of explicit consent (as deciding relatives may have no notion of the deceased's will in the matter at all).

On the above basis, it could be asserted that one can quite legitimately root such a law in a policy of promoting the autonomy of the deceased, but the perception of many within society is that this does not represent any form of valid, let alone ideal, consent. This in turn leads to allegations of 'taking' of organs by the State and an avoidance of any requirement for individual consent, which is potentially extremely damaging to the basis of trust, upon which a system of organ donation depends. This was a particular concern of the Organ Donation Taskforce in its second report, which recommended that opting out should not be adopted in the UK at that time.[10] Nonetheless, most European legal systems incorporate presumed consent policies, although they are much less common in Africa, Asia, and North America.

Mandated choice

Mandated choice is a strategy requiring individuals to record their wishes regarding organ donation after death at some stage(s) in their lives. It is a notion which has been mooted as a policy option for some while in the UK, but has only very recently come to fruition in the form of a pilot scheme. It has a foundation in various state jurisdictions in the USA, where it has achieved varied success. In Illinois, it is reported that since 2008, numbers on the organ donation register have swelled from 38% to 60% of the population.

In the UK, the policy has been implemented in the context of applications and renewals in relation to driving licences as from August 2011. It is assumed that driving licences will not be issued if the relevant organ donation question is not answered. The effects of such a strategy on donation rates are hard to gauge in advance, but is part of the notion of 'nudging' individuals in the direction of appropriate behaviours, a concept which appeals to the present coalition government. The underlying assumption is that as a majority of individuals declare themselves to be in favour of organ donation after death, and willing themselves to donate their own organs, that a majority will 'sign up' as donors under this system.

Some may be deterred by the idea of being forced to make an explicit choice, although it appears that there is an option available of declining to answer at the present time.[11] Some object to what is perceived to be coercion in such decision-making, as contrasted with our current voluntary system. However, our present silence itself makes an implicit statement about our wishes, whether we are aware of this or accept it, that is, that there is no objection to donation and that one is happy to let one's relatives to make this decision after one's death.[12] In other words, we are already making a tacit choice of one kind or another.

We should be mindful of the impact that such a new concept will have on prevailing practices and policies. At present, relatives are routinely asked to endorse donation even where the deceased has consented to donation before death (e.g. by entry on the NHS organ donor register). Would this continue even under a system which is at least purporting to respect the wishes declared on the driving licence form? If so, this may undermine the policy, and if not, relatives may be alienated from such decision-making contrary to tradition. And if one is allowed to 'defer' one's decision until later, there is the danger that this will be the automatic default for many who will merely postpone consideration of the subject.

Pre-mortem support

The medical treatment and support of patients at the end of their lives will frequently dictate the potential for donation of organs after death, and the quality of those organs for this purpose. In relation to controlled non-heart-beating donation (or so-called donation after circulatory/cardiac death, DCD), it may be necessary to initiate or continue life-supporting treatment which is not or is no longer considered to be of medical benefit to the patient while the logistics of retrieval and subsequent transplantation are put in place. Further, it may be necessary to further stabilize the patient in the interim before treatment is withdrawn and death is determined. With regard to heart-beating donors (donation after brain death), it will likewise be necessary to support the patient by way of artificial ventilation and other means during the period in which brainstem death ensues and is diagnosed, despite such measures not being of any medical benefit.

Obviously, if a competent (DCD) patient consents to such treatment him/herself, then there are no contentious issues. In the UK, in the absence of appointment under a (lasting/continuous) power of attorney giving authority over medical treatment decisions after loss of capacity, relatives have no power to consent to medical treatment on behalf of their adult kin who lack decision-making capacity (although they have such power in various other jurisdictions elsewhere). The power of relatives to consent to donation after death should not be confused with the question of consent to medical treatment of a living patient.

> *'The decision-maker [typically the responsible clinician]... must weigh up* all *factors which bear on the patient's interests [including] broader ethical, social, moral and welfare considerations'*

Where the patient lacks decision-making capacity (as is typically the case in the situations we are concerned with), decisions must be made in the patient's best interests. Statute in England and Wales (the Mental Capacity Act 2005) fails to define what best interests mean, but indicates what factors should be taken into account by the decision-maker and what feasible consultation should be carried out. While disconcerting to clinicians because of its lack of clear guidance, this lack of specificity does allow for the entire circumstances to be taken into account and provides flexibility in the application of legal principles. The law cannot hope to imagine and provide for the whole range of factors that may arise in any specific instance, let alone take into account the perspectives of all the relevant individuals.

When medical treatment is no longer considered to be in a patient's best interests, it should be withdrawn as there is no longer any legal justification for its provision. It is the *patient's* best interests only that matter. In the past, this was taken to relate only to a patient's medical interests. Perhaps it was for this reason, that it was the view of the Law Commission and the King's Fund Institute, that the practice of elective ventilation (whereby moribund patients on general medical wards were moved to intensive care units to enable ventilation to be instituted before the development of brainstem death) was illegal.

> *'Some interventions designed solely to enhance organ viability may not be considered in the person's best interests, even where the individual had a wish to be an organ donor'*

This led to the Department of Health sending a Circular to all centres in the mid-1990s requiring the practice to cease.

It is clear today that the decision-maker, who will typically be the responsible clinician in the hospital environs, must weigh up *all* factors which bear on the interests of the patient. The courts have initiated a shift towards a more holistic concept of a person's best interests and welfare. In *Re S*, the President of the Family Division remarked that a decision on best interests asks not only what is medically indicated, but also invokes 'broader ethical, social, moral and welfare considerations'.[13–15] The High Court has for instance held that it was in the best interests of a devout Muslim patient in a persistent vegetative state to be cared for at home, where her spiritual beliefs could be best respected, rather than in a nursing home where her physical needs could be better taken care of, and even though she could never be aware of her circumstances or environment.[16]

Moreover, the Mental Capacity Act 2005 in England and Wales and the Adults with Incapacity (Scotland) Act 2000 in Scotland *require* that, so far as is reasonably ascertainable, the person's past and present wishes and feelings, which would be likely to influence the person's decision if they had capacity, must be taken into account. In Northern Ireland, the situation is still governed by the common law in this sphere, although legislation is anticipated shortly.

Thus, the concept of best interests properly caters for a plurality of interests and is informed by the patient's own values, including altruistic aspirations.[17 18] This would include the wish (assuming that there is evidence to this effect on the register, or donor card, or by way of the testimony of relatives) to be an organ donor after death.[19] However, on a cautionary note, mechanistic reasoning should be avoided here, as the test is designed to ensure that the factors involved are weighed as regards each specific treatment decision. Where there are greater burdens attached to the treatment—such as some interventions designed solely to enhance organ viability, for example, femoral cannulation—these may not be considered in the person's best interests, even where the individual had a wish to be an organ donor.[20 21] Conversely, the potential harms to patients in such situations are limited by the likely moribund and permanently unconscious state of the individual at this time.

Declaration of interests

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