

Ethicolegal aspects of organ donation



Paul Murphy BA FRCA
John Adams MA MRCP FRCA

Key points

Organ donation should be seen as one of the end-of-life care options available to patients.

The current legal framework for organ donation after death in the UK is that of a hard opt-in.

A soft opt-out system of consent will be in operation in Wales by 2015.

Legislation describing decision-making on behalf of patients who lack capacity underpins the UK legal framework for organ donation after circulatory death.

In the UK, clinicians are provided with a comprehensive and robust professional, legal, and ethical framework for donation after circulatory death.

Deceased organ donation is frequently considered to lie at the interface between a critical care clinician's primary and non-negotiable obligations to the care of a dying or dead patient and a broader and less well-defined responsibility towards society's need for suitable donor organs for transplantation. This transition can generate conflicts, real or apparent, which in turn become barriers to interventions that might otherwise promote deceased donation. In its 2008 report *Organs for Transplants*, the UK Organ Donation Taskforce, mindful of these obstacles, recognized an urgent need 'to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and able to work within a clear and unambiguous framework of good practice'.¹ Since the publication of the Taskforce report, much has been done to assemble such a framework. For instance, professional bodies have produced 'consensus' statements on donation after circulatory death (DCD) and the care of potential donors identified in emergency departments.² In addition, relevant governmental agencies have provided legal guidance on DCD,³ while the UK Donation Ethics Committee (UK DEC) has begun to consider a range of issues relating to deceased donation, organ allocation, and transplantation, including DCD.⁴

None of these recent developments and publications has been dependent upon new primary legislation or radical shifts in the ethical landscape of critical care practice. Rather, they are the product of focused collaboration between clinical, ethical, and legal experts working with contemporary interpretations of existing UK professional, ethical, and legal standards. What has thereby emerged is a framework of practice that both protects and empowers clinicians to more effectively satisfy the legitimate wishes of an individual to donate their organs after death.

Legal framework for deceased donation in the UK

The UK has three separate legal systems, namely those of England and Wales, Northern

Ireland, and Scotland. While the legal system of Northern Ireland is heavily based upon common law and is closely similar to English law, Scottish law is more distinct.

In broad terms, the legislation which supports deceased donation in the UK governs two processes:⁵

- the removal of organs for the purposes of transplantation after death, and
- decision-making on behalf of critically ill patients who lack capacity.

Removal of organs for the purposes of transplantation

The legislative framework for donation in the UK is that of a hard 'opt-in' system of consent. The Human Tissue Act 2004, which governs practice in England and Wales, specifically uses the term 'consent' (although it does not equate with or require the standard of *informed* consent as it is used elsewhere in medical practice). The Human Tissue (Scotland) Act 2006 reflects this distinction explicitly and uses the term 'authorisation' rather than consent. Practice in Northern Ireland is governed principally by common law, although broadly it follows the legal principles that are applied elsewhere in the UK.

Primacy of an individual's wishes

Both the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 give primacy to the wishes of the individual, however, they have been stated and recorded. The Acts recognize that a wish to donate may have been recorded or stated in various ways—verbally, by having a Donor Card, in writing or via the various means of accessing the NHS Organ Donor Register (ODR)—all of which are regarded as equally valid forms of consent (or in Scotland 'authorisation') for organ retrieval after death.

Role of the family in consent for organ retrieval

A family has no authority at law to overturn the known wishes of an individual, and in

Paul Murphy BA FRCA

Department of Anaesthesia and Critical Care
The General Infirmary at Leeds
Leeds LS1 3EX
UK
Tel: +44 (0)113 3926345
Fax: +44 (0)113 3922645
E-mail: paul.murphy@leedsth.nhs.uk
(for correspondence)

John Adams MA MRCP FRCA

Department of Anaesthesia and Critical Care
The General Infirmary at Leeds
Leeds
UK

Table 1 Family consent and authorization for organ donation: ranked order of those in a qualifying relationship with the potential donor as defined by relevant primary legislation

Human Tissue Act 2004—England, Wales (and Northern Ireland)	Human Tissue (Scotland) Act 2006—Scotland
Spouse or partner	Spouse or civil partner, living with the adult as husband or wife or in a relationship which had the characteristics of the relationship between civil partners and had been so living for not less than 6 months
Parent or child	
Brother or sister	Child
Grandparent or grandchild	Parent
Niece or nephew	Brother or sister
Stepfather or stepmother	Grandparent
Half brother or sister	Grandchild
Friend of long-standing	Uncle or aunt
	Cousin
	Niece or nephew
	A friend of long-standing of the adult

Scotland families who object are required to sign a disclaimer in which they recognize that they have over-riden their loved one's wishes. The role of those close to the individual is first to help define the known or likely wishes of an individual. However, if the wishes of the individual are not known or cannot be determined, authority for decision-making passes to a nominated representative (England and Wales only), and then to a person in a qualifying relationship with the individual (Table 1).

Paediatric donation

Both Acts recognize the validity of the wishes of competent minors. Where the wishes of the individual are not known or the minor was not competent to deal with the issue, consent passes to those with parental responsibility or in their absence to an individual in a qualifying relationship.

The NHS Organ Donor Register

As far as the law is concerned, registration on the ODR represents consent or authorization for organ retrieval after death. The ODR should be checked before raising the possibility of donation with a family, with the expectation being that if a wish to donate has been registered any subsequent discussions with the family will be (sympathetically) based upon consent having already been given.

There is no age restriction for self-registration or self-withdrawal from the register. A parent can register their child or a child for whom they have parental responsibility, providing that the child is under the age of 16 years. Alternatively, a child can register themselves. Children under the age of 12 years at the time of registration are assumed to have been registered by their parents, while those of 12 years and over are assumed to have self-registered. As a consequence, while the parents of a child under the age of 12 years at the time of registration can withdraw this consent, if the child was 12 years or over then parents must provide evidence that they (rather than the child) were responsible for the registration should they seek to reverse it.

Decision-making on behalf of patients who lack capacity for decision-making during their final illness

Although organ retrieval occurs after death, it is sometimes necessary for donation to be considered—and adjustments to end-of-life care made—before the patient has died. The clearest example of this in the UK is controlled DCD, in which organ retrieval occurs after death that follows a planned withdrawal of cardio-respiratory treatments that are considered to be of no overall benefit to a gravely ill patient. In such circumstances, it is invariably necessary to delay treatment withdrawal until the arrangements for organ retrieval have been completed, to take samples of blood for microbiological screening and tissue typing, and possibly also change the location of treatment withdrawal (for instance, when the journey from a critical care unit to an operating theatre is too long or complicated). There are also other examples. For instance, is it permissible to admit to critical care a gravely ill patient with a catastrophic acute brain injury, with no prospect of survival, simply so that they can be stabilized, and their donation potential assessed and brainstem death tests performed? All are examples of interventions seemingly directed more towards the interests of a transplant recipient than those of a dying patient, thereby generating uncertainty over their lawfulness.

The primary legislation which governs the care of adult patients who lack the capacity to make decisions for themselves is the Mental Capacity Act (2005) and the Adults with Incapacity (Scotland) Act 2000. While it is clear from both Acts that it is only the patient's interests that count, it is also clear that such interests require reference to *all* factors affecting the person's interests and in particular the person's past and present wishes and that the decision reached should be a function of all the circumstances of the individual case. For instance, the Mental Capacity Act (2005) requires that

In determining what is in a person's best interests he [the decision-maker] must consider, so far as is reasonably ascertainable...

- the person's past and present wishes and feelings
- the beliefs and values that would be likely to influence his decision if he had capacity, and
- other factors that he would be likely to consider if he were able to do so

while Scottish legislation requires that

there shall be no intervention in the affairs of an adult unless the person responsible for authorizing or effecting the intervention is satisfied that the intervention will benefit the adult and such benefit cannot be achieved without the intervention.

and also that

in determining if any intervention is to be made, account must be taken of, amongst other things, the present and past

wishes and feelings of the adult so far as they can be ascertained...

Relevant Health Departments in the UK have now provided clinicians with legal guidance on controlled DCD. Thus, in its guidance, the Scottish government advised that

The concept of 'benefit' is likely to be wider than the person's immediate medical situation. It can reasonably be interpreted as permitting something which the adult could reasonably be expected to have chosen to do if capable, even though of a gratuitous or unselfish nature.

Similarly, the guidance issued from the Department of Health in London that is applicable to practice in England and Wales advised that

Delaying the withdrawal of treatment and changing a patient's location may be considered to be in the best interests of someone who wanted to be a donor if this facilitates donation and does not cause the person harm or distress, or place them at significant risk of experiencing harm or distress.

While recent legal guidance relates specifically to DCD, it can be argued that the principles upon which the guidance is based are equally applicable to other circumstances.

Ethical considerations

Donation after circulatory death

Although UKDEC has recently published very comprehensive guidance on controlled DCD,⁵ it continues to be ethically problematic for some clinicians. Such concerns focus upon the diagnosis of death, a perceived conflict of interests between decision-making over futility and the subsequent identification of potential organ donors, and whether extension or escalation of care after a declaration of futility has been made can ever be in the donor's best interests.

Diagnosis of death using cardio-respiratory criteria

For professional purposes, death is regarded as the irreversible loss of the capacity for consciousness combined with the irreversible loss of the capacity to breathe. Dying is almost invariably a process, and although it is not possible to accurately determine the exact point of death by using surrogate markers such as loss of cardio-respiratory function, there are strong societal and professional expectations that death should be diagnosed without unnecessary and potentially distressing delay. The cardio-respiratory criteria for the diagnosis of death in the UK as laid out by the Academy of the Medical Royal Colleges require 5 min of continuous cardio-respiratory arrest before a neurological examination is undertaken to confirm the absence of brainstem function and respiration.

It is important to emphasize that DCD does not depend upon a new definition of death and that the diagnosis of death is exactly

the same for DCD donors as it is for any other patient. Some clinicians have raised concerns about the possibility of return of cardiac function (and by implication cerebral perfusion) during the retrieval process, as a consequence of either so-called 'auto-resuscitation' or in response to a retrieval-related intervention.⁶ Available evidence indicates that within the context of treatment withdrawal, where there is no intention of attempting cardio-pulmonary resuscitation, no case of spontaneous return of cardiac function after 5 min of continuous asystole has been reported.⁷ Furthermore, UK guidance explicitly prohibits any retrieval intervention that risks restoration of cerebral blood flow.² Thus, although beginning organ retrieval so soon after asystole may generate anxiety, clinicians who adhere to UK guidance can have considerable confidence that they are working to acceptable professional and ethical standards.

The possibility of cardiac transplantation from hearts retrieved from DCD donors has also proved controversial, with some arguing that the restoration of mechanical activity of the heart in the recipient renders invalid a cardio-respiratory definition of death. However, death applies to the person as a whole, not their individual organs, and is diagnosed after irreversible loss of integrated cardio-respiratory function rather than the capacity of the myocardium to contract after reperfusion.

Declarations of futility and conflict of interest

The majority of deaths in UK ICUs involve a decision to limit or withdraw treatments that are judged to be of no overall benefit to a patient.⁸ These decisions are, of course, integral to controlled DCD, and it is vital that both the public and the healthcare profession have confidence in such decision-making. Decisions regarding lack of overall benefit need to be made regardless of the need for a supply of organs to transplant and are ethical, providing that they are independent, robust, and not influenced by the need for organs. Thus, in its guidance on DCD,⁴ UKDEC advises that

Two senior doctors, one of whom should be a consultant, should verify that further active treatment is no longer of overall benefit to the patient.

Organ donation should only be considered after this declaration of futility has been made.

Organ-specific interventions: harm, best interests, and respect for autonomy

Warm ischaemic injury to the transplantable organs may be reduced by initiating novel therapies or interventions before the patients' death. This might include administration of heparin to prevent vessel thrombosis, vasodilators such as phentolamine to improve blood flow, antibiotics to reduce the likelihood of sepsis-related organ injury, or the insertion of intravascular cannulae to allow the rapid administration of organ preserving solutions once cardiac standstill has occurred. Although such manoeuvres are commonplace in other countries, their use is generally not

recommended in the UK,² despite the fact that they may improve organ viability.

The concepts of harm, best interests, and respect for autonomy are central to the ethical acceptability of such interventions. Some clinicians may be concerned that they are no longer acting in the patient's 'best interests' by continuing treatments or introducing new ones, once a declaration of futility has been made. However, such narrow views of 'best interests' based solely upon physical harm should be avoided, since they fail to adequately take into account the patient's wishes and beliefs.⁹ Furthermore, harm has two elements—the physical effects caused by an intervention (e.g. cannulation) and the emotional harm caused by ignoring a competent person's wishes about their end-of-life care. The possibility of facilitating donation provides a valid reason for considering the continuation of treatments that may have no direct physical benefit to the patient, as one can reasonably assume that the donor would wish for their organs to be in the best possible condition for the recipient.

It is acknowledged that the clinician's primary duty of care is to the patient and not the potential recipients. However, where a competent individual has made a choice to become an organ donor at the end of their life, respect for that individual's autonomy requires that this duty of care should include facilitation of that wish wherever possible. Although respect for autonomy may need to be balanced by other ethical principles such as non-maleficence (not intentionally causing harm), autonomy retains primacy. Indeed, there is clear precedence in modern healthcare of subjecting patients to potential harm for the benefit of others. This includes blood and marrow donation, live altruistic organ donation, so-called 'saviour siblings', and non-therapeutic research. Interventions aimed at optimizing organ function in the dying patient who wishes to become an organ donor are ethical as long as they do not cause or place the patient at significant risk of harm or distress. In the context of DCD, modest interventions to preserve organ function are unlikely to constitute a significant harm.

Future developments in controlled DCD

Warm ischaemia currently limits organ retrieval from DCD donors, and it is legitimate for retrieval teams to consider how this might be limited or reversed.¹⁰ Thus, and with strict safeguards, lung retrieval from DCD donors is now established in the UK.² Some abdominal retrieval teams are exploring the benefits of *in situ* normothermic reperfusion of the splanchnic organs before explantation, while others are considering DCD heart retrieval, both of which would benefit from systemic heparinization of the potential donor before death. Current legal guidance for the UK³ implies that systemic heparinization might be unlawful, since it could place a person at risk of serious harm. However, it is likely that risks of heparinization have been overstated, and in any event, these risks need to be balanced against the possibility of increasing both the number and quality of organs that might be retrieved and thereby better honouring the individual's wish to be an organ donor.

Consent

As noted above, the UK operates a hard opt-in system of consent for deceased organ retrieval. Consent rates in the UK are around 60% overall and are much lower in some minority ethnic groups. These rates have remained static over the last decade and fail to match the apparent level of public support for deceased donation as revealed by opinion polls. Consent rates are much higher in many other developed countries, with there being a weak association between opt-out systems of consent and higher donation rates. The UK Potential Donor Audit reveals consent to be the biggest single opportunity in the donation pathway to increase donor numbers. Given the apparent inadequacy of current arrangements, there have been several calls for consent processes in the UK to be reviewed.

NHS Organ Donor Register

The ODR is one means by which individuals may record their wish to donate organs and tissue after death. Registration is simple and there is no requirement to read any information about the different types of organ donation and the way they may affect end-of-life care. Some have argued that this approach undermines our commitment to informed consent and autonomy, particularly with regard to interventions made while an individual is dying but not yet dead. However, others have countered that actions taken to facilitate *deceased* organ retrieval do not need to meet such a standard of consent,¹¹ noting that the public are generally supportive of the current system and remain largely unconcerned about the ethical issues raised by clinicians.

The impact of the ODR on donor rates is uncertain, however. Only a third of the UK population have registered their consent to donation on the ODR. It follows that the majority of actual donors have not used it to record their wishes. Furthermore, there has been no demonstrable increase in consent rates since the introduction of the ODR in 1994. Indeed, consent/authorization rates were higher in the year of its introduction than they are today. Furthermore, there is a concern that with increasing awareness of the ODR and continuing focus on honouring an individual's wishes, that absence of registration will be interpreted as a wish not to donate and result in a family refusal. Many countries with higher levels of consent than the UK do not have a donor register.

Presumed consent

With consent rates that currently fail to match both public expectations and those reported from elsewhere in the world, many groups (including the British Medical Association)¹² have called for a system of presumed consent to be introduced into the UK. The Organ Donation Taskforce advised that while a system of soft opt-out (i.e. one in which the family of a potential donor would retain the opportunity to influence decision-making) would be both ethical and legal, it should not be referred to as one of consent, since consent cannot be presumed. Once again, it is noteworthy that the public are largely in favour of such a system, albeit

grounded in an assumption that it would result in a substantial increase in the number of donors. While it could be argued that it is morally unacceptable to perpetuate the current UK system, particularly when consent/authorization rates fall short of apparent levels of public support for donation, superior efficacy of a given policy is not alone sufficient to recommend it from an ethical standpoint. Those who oppose a soft opt-out system maintain that for it to be ethically acceptable, it would need to be demonstrated that organ donation is a basic life goal for the majority of the population and that where consent is obtained, the individual is fully informed. Despite these reservations, it seems certain that an opt-out system will be introduced into Wales in the relatively near future.

Mandated choice

Under this proposal, all competent adults are required to make a declaration about their wishes regarding organ donation. If that person would rather not make that choice, they would have the option to leave the decision to designated family members at the time of their death. Advantages include the provision of more information (and therefore more informed choices), the stimulation of wider public debate and personal family discussion, and a possible reduction in emotional stress for relatives and staff when having discussions about potential organ donation. However, trials of mandated choice in the USA and elsewhere have been unfavourable and as a result abandoned.

Incentives for donation

One feature of the so-called Spanish model for donation, where family consent rates are over 85%, is that consenting families are offered reimbursement of funeral expenses. An independent bioethics group has proposed that a similar system be introduced into the UK,¹³ although this may be in conflict with one of the guiding principles around organ donation and transplantation recently published by the World Health Organization, namely

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned. The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving or supplying human cells, tissues or organs for transplantation.

Taking a somewhat different approach, and despite considerable opposition from religious groups opposed to donation after brain death, recent legislation in Israel now gives some preferential access to transplantation to individuals who have joined the state donor register and to the relatives of actual deceased donors. Such approaches serve to satisfy to a degree those with moral concerns

over the so-called 'free rider'—an individual who is prepared to accept an organ, but unwilling to donate.

Collaborative requesting and the role of the family

All of the proposals above seek to in some way influence the views of individuals/society before the possibility of donation becomes a reality. However, approximately one-third of families decline the option of donation even though they themselves support donation or indeed were aware that their loved ones did. It is possible, therefore, that a family's response to the donation approach can be unintentionally and adversely impacted by the way in which it is conducted and, therefore, be amenable to modification.¹⁴ It is suggested for instance that a genuine wish to consider donation might be thwarted if the approach is made before a family have accepted the inevitability of their loss, if the approach is made using negative or apologetic language, or if closed questions, which can arbitrarily result in a premature but nevertheless irretrievable refusal, are used early on in the conversation. Transplant coordinators have considerable expertise in this regard, and for this reason in its guidance on organ donation, the National Institute for Health and Clinical Excellence (NICE) recommends that wherever possible the clinical team in the donor hospital and attending specialist nurse for organ donation (donor transplant coordinator) plan for and conduct the family approach collaboratively.¹⁵ While clinicians are understandably sensitive to any suggestion of coercion or the involvement of individuals with a vested interest in donation, NICE places emphasis on this providing a better service for the donor family and the donor themselves.

Directed donation

Deceased donation is founded upon the principle that the gift of donation is unconditional and that the organs are assigned to those in greatest need, according to agreed and transparent allocation protocols. There is widespread agreement that donors or donor families should not be permitted to place conditions on a donation that block the allocation of organs to groups in society on the basis of the recipient's creed, colour, sexual orientation, etc. However, there have been occasions when a member of the family of a potential deceased donor is themselves in need of an organ transplant and that their receipt of an organ is requested during the consent/authorization process. Working on the basis that a deceased donor would have wished to direct an organ to a family member, such directed donation—or perhaps more accurately directed *allocation*—is now supported in the UK, with the following safeguards:

- the donation must be otherwise unconditional (i.e. other transplantable organs are made available to the general recipient pool without restriction),
- unrelated recipients on super-urgent waiting lists take priority over the related recipient, and
- the related recipient must be on a UK transplant waiting list, a suitable match for that organ, and a close friend/relative of the deceased.

Conclusion

Perhaps the most important contribution of the Organ Donation Taskforce was the proposition that the option for donation should be regarded as a routine part of end-of-life care. The professional, legal, and ethical guidance that has followed represents a framework of practice in which critical care staff can have considerable confidence. While challenges inevitably remain, in presenting donation as part of the care that someone is entitled to have considered when they die, clinicians will do better for their patients and for society as a whole.

Declaration of interest

P.M. is a National Clinical Lead for Organ Donation at NHS Blood and Transplant.

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Please see multiple choice questions 13–16.