



Two fundamental ethical and legal rules for deceased organ donation

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Learning objectives

By reading this article, you should be able to:

- Discuss the two main legal and ethical rules upon which deceased organ donation is based: the *dead donor rule* and the *consenting donor rule*.
- Describe the legalities of consent for organ donation, including opt-out and deemed consent legislation.
- Explain the limits of consent and why there is a need for professional and ethical practice guidance.

Organ failure and the need for transplantation remain high in all countries. Unmet need can lead to death on the transplant waiting list or commercially driven transplantation. A number

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Key points

- Deceased organ donation is built upon two ethical and legal rules: the *dead donor* and *consenting donor* rules.
- The *dead donor rule* is standardly formulated as the rule that ‘donors must be determined to be dead before their organs are recovered’.
- Worldwide, there are different legislative models for the *consenting donor rule*: opt-in, opt-out, hybrid and soft or hard enforcement.
- Consent to donation may legally permit donation, but it does not mandate that donation occurs or dictate what clinicians should do in a particular circumstance. Clinicians’ actions should be guided by professional standards, operating within the boundaries set by law, and based on science, ethics and cultural expectations.

of international resolutions and declarations have called on each country to strive toward self-sufficiency in organ donation and transplantation. However, no country has yet achieved this goal. We therefore face common barriers to increasing rates of donation across all social groups, ethnicities and religions. Any response cannot be at the expense of the two ethical and legal rules upon which deceased organ donation is based.

The first rule is the *dead donor rule* (DDR). This rule was coined as a phrase by John Robertson in 1988, but the principle it is based upon is much older.¹ The *Journal of the American Medical Association* published a landmark paper in 1968 from the Ad Hoc Committee of the Harvard Medical School, which established ‘irreversible coma’ as an acceptable criterion for

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diagnosing death. Less well known is that in the same edition of the journal, the Judicial Council of the American Medical Association published ethical guidelines for organ transplantation.² Two ethical rules emerged from the guidance that have been fundamental to transplantation policy ever since. Firstly, the rule that would become the DDR: ‘When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient’s physician’. Secondly, the rule that ‘full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory’. This second rule, although not officially phrased as such, can be understood as the *consenting donor rule*—someone must have consented to the organ removal.

This paper explores the two rules further, providing an international context on current challenges and how different jurisdictions have sought to uphold the organ donation rules that are as old as transplantation itself. [Supplementary material](#) summarising current and historical guidance, legal cases and UK donation statistics referred to within this article is available.

Dead donor rule

The standard formulation of the DDR is that ‘donors must be determined to be dead before their organs are removed’, but a number of alternative formulations have emerged over time.³ One is narrow in scope, where the DDR is understood to be merely a prohibition on killing the patient for organ donation. On this understanding of the rule, if a dying patient had both kidneys removed, followed by the withdrawal of life-sustaining treatment (WLST), one could still theoretically satisfy the DDR, as death would follow treatment withdrawal (over hours) and not death by renal failure (over days).⁴ Needless to say, such an interpretation and application have not been implemented. An alternative and broader formulation of the DDR would prohibit any actions for organ donation (e.g. consulting the organ donor register and maintaining stable physiology) whilst the patient is still alive.⁵ [Table 1](#) illustrates how the two types of deceased organ donation may satisfy these differing formulations of the DDR. What is immediately apparent is that donation rests upon accurate and accepted criteria for diagnosing death.

Donation after neurological death

For donation after the diagnosis of death using neurological criteria (donation after neurological death or donation after brain death), provided neurological criteria for death are legally accepted in the relevant jurisdiction and the criteria are appropriately met, the DDR is fully satisfied. Neurological criteria for death have been legally accepted in many nations since the 1960s and 1970s, and the clinical criteria have not significantly changed over that time. However, there has also been an international conceptual shift in the definition of death toward the UK position (emphasising brainstem, breathing and consciousness) (see [Table 2](#)), and including, as in this paper, a move away from the confusing term ‘brain death’.

One late 20th century definition of death was that death is the irreversible cessation of the integrated functioning of the organism as a whole. The idea that neurological death satisfied this definition was based on the false assumption that the brain is the integrator of the organism’s vital functions (e.g. heart).⁶ A better rationale is emerging, which is that the brain is what makes us the people that we are. If a person’s brain were removed from the skull and destroyed, the person would be dead even if the rest of the head and body were sustained artificially. This has been the UK position since the 1970s, which has held that whatever the mode of its production, ‘brain death’ represents the stage at which a patient becomes truly dead. One criticism of this concept is that neurological death reflects a Western Cartesian view (mind and body are separate) rather than the holistic views typical of other Eastern cultures and religions.⁷

Another criticism is that in some statutes, diagnosing death using neurological criteria (DNC) requires the irreversible cessation of all functions of the entire brain (USA) or all functions of the brain (Australia). Recognising that some neurological functions (such as hypothalamic function) may persist after DNC, the American Academy of Neurology has defended the *status quo* by arguing that the preservation of some of these functions does not invalidate the determination of brain death. However, a declaration of death when there is persisting brain function does not comply with the wording of USA statutes and so remains open to legal challenge. As endocrine functions of the brain do not relate in any way to the presence of consciousness and arousal, it is desirable to

Table 1 Types of deceased organ donation and their satisfaction of differing formulations of the dead donor rule.

Formulations of the dead donor rule	Satisfaction of the dead donor rule	
	Donation after the diagnosis of death using neurological criteria	Donation after the diagnosis of death using circulatory criteria
Narrow: ‘the killing of patients for organ donation is prohibited’	Yes	Yes, provided procedures before death (e.g. heparin) do not hasten death
Standard: ‘donors must be determined to be dead before their organs are removed’	Yes, provided neurological criteria for death are accepted	Yes, provided standard circulatory criteria for death are accepted
Broad: ‘procedures for organ donation should not be initiated whilst the patient is still alive’	Yes, procedures for donation can be delayed until after death	Uncontrolled: Yes, provided standard circulatory criteria for death are accepted Controlled: No, as procedures for organ donation (e.g. blood tests for organ matching) must occur before treatment withdrawal and death

Table 2 Evolving definitions of death over time (see further reading, [Supplementary material](#)). UDDA, Uniform Determination of Death Act.

Document	Definition of death
Ad Hoc Committee of the Harvard Medical School, 1968, USA	'Our primary purpose is to define irreversible coma as a new criterion for death... A permanently non-functioning brain represent[s] the death of the individual'.
Conference of Medical Royal Colleges and their faculties, 1976, UK	'Permanent functional death of the brain stem constitutes brain death'.
Conference of Medical Royal Colleges and their faculties, 1979, UK UDDA, 1981, USA	'Whatever the mode of its production, brain death represents the stage at which a patient becomes truly dead'. 'An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards'.
Academy of Medical Royal Colleges, 1998, UK	'Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person. Thus, it is recommended that the definition of death should be regarded as "irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe." The irreversible cessation of brain stem function (brain stem death) whether induced by intracranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore brain stem death equates with the death of the individual'.
Academy of Medical Royal Colleges, 2008, UK	'Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe... The irreversible cessation of brain-stem function whether induced by intracranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore irreversible cessation of the integrative function of the brain-stem equates with the death of the individual and allows the medical practitioner to diagnose death'.
International Guidelines for Determination of Death Phase 1 participants, in collaboration with the WHO, 2014	'Operational definition of human death: Death is the permanent loss of capacity for consciousness and all brainstem functions. This may result from permanent cessation of circulation or catastrophic brain injury. In the context of death determination, "permanent" refers to loss of function that cannot resume spontaneously and will not be restored through intervention'.
American Academy of Neurology (AAN), 2019, USA	'The AAN endorses the UDDA definition that brain death has occurred when the irreversible loss of all functions of the entire brain, including the brainstem, has been determined by the demonstration of complete loss of consciousness (coma), brainstem reflexes, and the independent capacity for ventilatory drive (apnea). It recognizes that neuroendocrine function may persist in patients with irreversible injury to the brain and brainstem'.
World Brain Death Project, 2020	'[Brain death/death by neurologic criteria (BD/DNC)] is defined as the complete and permanent loss of brain function as defined by an unresponsive coma with loss of capacity for consciousness, brainstem reflexes, and the ability to breathe independently. This may result from permanent cessation of oxygenated circulation to the brain and/or after devastating brain injury. Persistence of cellular-level neuronal and neuroendocrine activity does not preclude the determination. In the context of death determination, "permanent" refers to loss of function that cannot resume spontaneously and will not be restored through intervention'.

see the statutes amended to bring them more into line with the irreversible loss of brainstem function criterion used in other countries, such as the UK.⁸ There is growing worldwide support for updating the definition of death.⁹

Even with an accepted worldwide rationale, and updated statutes, not all families will be willing to accept either the concept or the finality of a diagnosis of DNC. In a world where experts are less trusted, it is perhaps no surprise that legal challenges to neurological criteria for death are therefore increasing in frequency. To date, none have been successful in reversing a DNC diagnosis.⁸

Donation after circulatory death

One might have thought, therefore, that donation after the diagnosis of death using circulatory (cardiorespiratory) criteria (DCD) would be less controversial and satisfy the DDR more easily. However, that is not the case. [Table 1](#) highlights the concern that medications that may be given before death, such as heparin and phentolamine, might hasten death.^{10,11} It is theoretically possible that heparin will cause further bleeding, especially given that patients eligible for DCD with brain haemorrhage and trauma form the largest pool of

potential donors; the use of phentolamine may cause hypotension.¹² The 2009 England and Wales, 'legal issues relevant to non-heart beating organ donation' identified heparin as an intervention that places the person at risk of serious harm, and therefore is 'unlikely ever to be in the person's best interests'. The same position is taken in New South Wales in Australia (see [Supplementary material](#)). The rest of the world takes a different view, and pre-death heparin administration represents routine practice for DCD in many countries.

There is some debate concerning whether the circulatory criteria used in donation (particularly the 5 min observation period to ensure the possibility of autoresuscitation has passed) are acceptable for diagnosing death.^{11,13,14} This debate is more problematic in countries that have no nationally established criteria for diagnosing death outside of donation contexts, such as in the USA, Canada and Australia. The UK's position is stronger, as it uses the same criteria for diagnosing death irrespective of organ donation. The 5 min standard was actually proposed in 1846 by Eugène Bouchut, well before organ donation was considered possible.¹⁵ Bouchut advocated the use of the stethoscope as a technological aid to diagnose death. When the heartbeat was absent for 5 min, a person could be diagnosed dead. He also considered that it should be doctors who diagnose death (previously it had been family members and priests). The Academy of Sciences in Paris, France accepted Bouchut's view that this would aid public safety in preventing premature burial and assist with death certification and coronial investigations.

The debate about the criterion of a 5 min observation period often centres around the terms 'irreversible' and 'permanent'.^{16–19} 'Irreversible' is the term most commonly seen in statutes or codes of practice, but this is perhaps a historical anomaly, as the earliest documents often used the two terms interchangeably. More modern usage defines *irreversible* as 'pertaining to a situation or condition that will not or cannot return or resume' (i.e. even with advanced resuscitation techniques, the circulation cannot be restored by anyone under any circumstances at a time now or in the future) and *permanent* as 'pertaining to a situation or condition that will not return to its previous state' (i.e. the circulation will not resume spontaneously and will not be restored through intervention) (Table 2). A concept of permanence for diagnosing death is in keeping with usual hospital practice. A diagnosis of death is not dependent upon a failed resuscitation attempt or waiting a prolonged time after circulatory

arrest until the patient becomes theoretically impossible to resuscitate (possibly several hours if extracorporeal membrane oxygenation [ECMO] were being used).²⁰ It is more usual for doctors to diagnose death using the criterion of permanence rather than irreversibility, and therefore, if professionally and legally accepted, donors after the diagnosis of death using circulatory criteria do satisfy the standard formulation of the DDR.

An associated challenge is the question of whether, if circulation to only part of the body was restored, this would invalidate the diagnosis of death using circulatory criteria. UK definitions and criteria for death are very clear that it is cessation of cerebral perfusion that counts, not perfusion to other parts of the body. This has allowed the UK to develop normothermic regional perfusion (NRP) techniques, where an ECMO-like circuit is used after death to perfuse abdominal organs and restore their function whilst simultaneously isolating the restored circulation from the thoracic organs.²¹ Some countries, notably Spain and France, have also developed NRP programmes, but others, like Australia and the USA, have been limited by the statutory requirements in their definitions of death prohibiting the restoration of circulation in the body. A number of European centres, such as the Royal Papworth Hospital NHS Foundation Trust in the UK, have piloted NRP for thoracic organs with accompanying isolation of the cerebral circulation, which leads to the heart restarting in the body after death, but without cerebral perfusion.²² The advantage of this technique for DCD heart donation, over the more common technique (in the UK and Australia) of direct and rapid retrieval of the heart and placing the heart on a machine perfusion device outside of the body, is a hoped-for reduction in warm ischaemic damage and better functional assessment before organ retrieval.²² Both abdominal and thoracic NRP rely upon interventions that prevent cerebral circulation being restored after death. A Canadian and UK proposal was recently published, which included a detailed anatomical examination to prevent any unexpected collateral blood flow to the brain.²³

Perhaps a greater challenge for DCD is when a broad formulation of the DDR is considered (Table 1). Here, the consideration is not whether the patient is dead when organ recovery commences, but whether the patient is dead before actions or procedures necessary for organ donation commence. In *uncontrolled DCD* (death diagnosed after failed cardiopulmonary resuscitation in the emergency

Table 3 Examples of systems for organ donation consent.

System	Definition	Example countries or nations
Hard opt-in	Only those who register in life can donate. First-person authorisation; opt in is legally binding.	Japan 1997 (now opt out); USA, with court case if family tries and overrules (cases of this nature are still very rare in the USA)
Soft opt-in	Register/card completed in life expressing decision to be a donor after death, but family can overrule	Australia, Canada and USA
Hard opt-out	If no expressed decision in life, family chooses	
Soft opt-out	Unless opted out, (register/card) donation will go ahead irrespective of family's views	Singapore and Austria (in reality, clinical practice often very different from law)
Soft hybrid	Donation will go ahead unless opted out (register/card/verbal) or family's opposition	Most common system worldwide: Spain, France, Portugal, Argentina and Poland
	Mixture of soft opt in and opt out, allowing registration/card for both and allowing family to overrule	England, Wales, Scotland (from 2021), Nova Scotia (from 2021) and The Netherlands (often occurs when a soft opt out is introduced into a soft opt-in jurisdiction)

department), donation procedures can be delayed until after death. But, for the main type of DCD in the world, *controlled DCD*, which follows a decision to WLST, certain donation procedures (e.g. blood tests for organ matching, delaying withdrawal until the organ retrieval team is present and ready, potentially moving the patient from the ICU for WLST) must occur before death. However, whilst a broad DDR formulation can never be satisfied in controlled DCD, ethics, law and professional practice have implicitly advanced the view that it is the *consenting donor rule* that is the pre-eminent consideration in living patients in the hours before their death and subsequent donation after the diagnosis of death using circulatory criteria (see [Supplementary material](#)).

Consenting donor rule

Two rules must be met for organs to be removed from a deceased patient: he or she must be dead (see the aforementioned analysis), and someone must have consented to the removal of organs. The two-key decision makers regarding consent to donation are the patient and the patient's family, which can comprise many different decision makers. Sometimes, there is a disagreement between family members about whether donation should take place, and sometimes the collective family decision can contradict that of the patient. In such situations, the question of which decision is decisive depends on the model of consent used in a given jurisdiction. Worldwide, the different systems for organ donation consent are opt-in, opt-out, hybrid and either soft or hard enforcement ([Table 3](#)). Since the introduction of opt-out in Wales in 2015, England in 2020 and Scotland from 2021, in addition to maintaining the ability to opt-in, the UK is best described as having a soft hybrid system.

Consent law

Opt-in

Many countries operate an 'opt-in' consent system, where people are encouraged to register their consent to donation if they want to donate.^{24–27} This system might be when applying for a driver's licence or other services, or through registering online. Whilst such methods of registering do create a record of consent, and are quick and convenient, the very ease with which it is possible to register consent can create problems when it actually comes to the point of donation. Such consent is very basic; yet, donation is a complex process coinciding with an emotional crisis for the family, something individuals may not have appreciated when they consent.

Despite the fact that consent has been registered, a proportion of families (approximately 10% in the UK each year) will overrule, override or veto donation. This is often because they had no idea that their relative wanted to donate. However, in other cases, families may genuinely believe that a person did not want to donate. Perhaps because they believe their relative 'ticked a box' without thinking and donation was not in character, or because they recall a recent conversation where the person voiced disapproval of donation. In such cases, this might constitute an override of consent, but could be considered provision of new evidence of the person's decision not to donate.

Dealing with such situations can be difficult for healthcare professionals; they do not want to upset families further, but also wish to respect the patient's 'dying wish' or decision.

Furthermore, every time a family overrules donation, organs that could have saved lives are not utilised, and there is evidence that some families come to regret overruling donation.²⁸ Because of these factors, an attempt is normally made to encourage families to respect the registered decision of the deceased, but in most countries, professionals will not go ahead with donation if the family remains steadfast in its opposition. Only in a few countries is there a 'hard' opt-in, where any recorded consent will be followed even if the family very strongly opposes it. In the USA, on occasion, court action is sometimes taken by hospitals and donation organisations to enforce an opt-in of the deceased, particularly in states that have enacted 'first-person authorisation' consent laws.²⁹ The problem with such strong protections of individual consent is that they may not be based on strong evidence, again because of the ease with which consent can be registered.

Actively opting in whilst alive is not the only means by which consent can be gained. If there is no evidence of consent (or refusal), a family member can consent to donation on the patient's behalf. In the UK, there are legally established hierarchies of different family members for organ donation consent, with spouse or partner (including civil or same-sex partner) at the highest and friend of long standing at the lowest. A disadvantage of opt-in systems is that families are often reluctant to consent on a patient's behalf if he or she did not consent whilst alive; they fear that they might give consent to donation against the wishes of their dead relative. Until the introduction of opt-out in the UK, only half of families asked to consent when the patient had not consented in life agreed to do so.

Opt-out

Because of all the problematic issues affecting opt-in consent, some jurisdictions have now moved to, or are transitioning towards, 'opt-out' systems, joining many other nations who only ever had opt-out. In an 'opt-out' system, it is presumed that a person wants to donate after death unless he or she has registered or expressed an objection. In addition to avoiding some of the aforementioned pitfalls of opt-in, this approach has the perceived advantage of 'normalising' donation by making it the default position. However, some ethical issues are raised by so-called presumed consent systems.

Firstly, it is often argued that such systems amount to the government taking control of people's organs.³⁰ This simplistic objection is misplaced; control still resides with individual citizens, but the difference is that they do now need to actively refuse to donate, rather than actively choose to donate or let their relatives decide. In that sense, the system is more demanding for people who are opposed to donation, but it still leaves the choice in the hands of the people.

Secondly, a related issue is that people might not know that they need to opt out. In Wales, the first of the UK nations to implement 'deemed consent' legislation, as many as 20% of residents could not describe the new consent system 2 yrs after it was introduced.³⁰ If people are not adequately informed about the need to register refusal to donate, that calls into question the validity of any deemed consent.

The third issue, and a main ethical problem with opt-out, concerns the family overrule and the removal of family consent. Deemed consent systems work by presuming consent for anyone who has not registered an objection; this avoids some of the problems associated with opt-in consent, but retains and enhances the concern about reliability of consent.

Under opt-in, an active choice was made to consent; under opt-out, the evidence of a person's willingness to donate is considerably weaker.

Both opt-in and -out systems raise challenges for health-care professionals. They must consider what the evidence regarding consent tells them about the patient's end-of-life views and balance that against the views of and information provided by the family to determine whether organ donation is (still) in the patient's best interests (or continued best interests, if the patient is already dead; see the next section). Whether opt-in or -out consent is used, or whether it is the family that consents to donation, the fact that consent has been obtained and the family does not object does not mean that donation will go ahead if it is judged that doing so would be against the patient's best interests. An example might be deciding on the acceptability of an invasive procedure to facilitate donation, in a patient and family where the willingness to donate is present, but could be better characterised as 'donation yes, but not at all costs'. The 'yes' to donation is

legally permissive; it does not legally mandate that donation proceeds or create a carte blanche authority for all donation actions.

Professional guidance

When a clinician treating a potential donor actually needs to make decisions on what degree of interventions is acceptable to facilitate a donation, organ donation consent laws prove inadequate, particularly with regard to actions before death in DCD. This is especially true because aside from donation after assisted dying (Belgium, Canada, The Netherlands and Switzerland) and very rarely awake patients with severe respiratory or spinal pathology, all potential donors are unconscious and cannot be asked for specific consent for any proposed intervention. [Table 4](#) outlines potential pre-death donation actions in DCD, ranked, somewhat arbitrarily, according to the degree of intervention required. Consent law and guidance (as outlined previously) can only tell us whether someone wanted to, or had no objection to, become a donor after death. It does not necessarily give any indication of the strength of someone's desire to be a donor, or their willingness to have a donation action listed in [Table 4](#). By way of analogy, the law tells us what paddock we can graze in, giving broad boundaries to what is acceptable and what is not, but it is professional standards that tell us what grass we can eat and what clinicians should do in a particular circumstance. Professional standards, either written or unwritten, operate within the boundaries set by law, and are then based on science, ethics and cultural expectation. Such standards are what guide clinician actions in all areas, including deceased organ donation.

This was recognised in legal guidance for DCD produced in England and Wales in 2009. 'While registration on the [Organ Donor Register] provides consent for donation after death for the purposes of the Human Tissue Act(s), it cannot be viewed as advance consent to steps to facilitate [DCD]. It would, however, be important evidence of a patient's wish to donate'. As the guidance recognises, consent and transplant laws are of limited use for deciding on acceptable interventions before death, and it is other laws, such as laws relating to best-interest decision-making for alive patients who lack mental capacity (e.g. the *Mental Capacity Act 2005*), which are decisive for guiding clinicians caring for potential organ donors. Under such laws, 'best interests' is defined broadly to include the views and values of the patient and the patient's own wishes and feelings. It has also been held that 'best interests' is not restricted to the patient's 'self-interest' and 'could include altruistic sentiments and concern for others'. This means that patients can be acting in their own best interests when they act in the interests of others. In addition, it has been held that it is not necessary for the patient to be aware of the fact that his or her wishes have been carried out for something to be in the patient's best interests. Finally, it has been held that 'best interests do not cease at the moment of death' (see [Supplementary material for details](#)).

In England and Wales, consistent with the requirements of the law in these nations, DCD legal guidance states that, when deciding whether a proposed donation action is in the patient's best interests, 'clinical teams will need to balance the risk of harm against the knowledge that they have regarding a patient's wish to donate'. The UK Donation Ethics Committee, when providing ethical guidance for generic interventions before death, recommended that it was the strength of the

Table 4 Potential actions in DCD before death, ranked according to the degree of intervention required. DCD, diagnosis of death using circulatory (cardiorespiratory) criteria; ECMO, extracorporeal membrane oxygenation; WLST, withdrawal of life-sustaining treatment

Degree of intervention required	Donation action
Low	Blood tests (e.g. tissue typing) Delaying WLST Maintaining respiratory stability by alterations in mechanical ventilation Fluids or blood transfusion Medications to maintain cardiovascular stability (e.g. inotropes and anti-arrhythmics) Moving location for WLST Bedside radiological imaging (e.g. transthoracic echo and chest X-ray) Central venous or arterial catheter monitoring
Intermediate	Central venous or arterial catheter insertion Medications to improve transplantation outcomes (e.g. heparin, phentolamine and steroids) Distant but simple radiological imaging (e.g. CT) Simple biopsy (e.g. skin lesion) Reintubation ECMO catheter cannulation
High	Cardiopulmonary resuscitation Elective ventilation Complicated biopsy (e.g. brain) Distant but more complicated radiological imaging (e.g. MRI and coronary angiography) Cryopreservation for delayed donation in a future decade (this is a science fiction example to highlight the limits of considering consent to organ donation to be simple and binary)

patient's decision or wish to donate, gained from discussion with patient's family and friends, which should guide pre-death interventions. 'The stronger the evidence of the patient's desire to become an organ donor, the greater the weight this should be given in assessing whether a particular intervention would be in the patient's overall benefit'. Apart from the likelihood that evidence may be weaker, this need not be more complicated than in an opt-out environment, provided the role of the family is respected.

The Human Tissue (Authorisation) (Scotland) Act 2019, bringing in opt-out to Scotland in 2021, tries to give legal support for clinicians by listing acceptable pre-death procedures divided between Type A (routine and less-invasive procedures) and Type B (rare and more-invasive procedures). Even with this legal support, it can only tell a clinician what is legally acceptable to do, not what the clinician should do for a particular patient. The Scottish legislation enshrines in law the additional requirement of a 'duty to inquire' of the nearest relative, and others who may be able to provide evidence, regarding the potential donor's most recent views in relation to organ donation and the carrying out of pre-death procedures.

The consenting donor rule is therefore not just about the basis for organ donation consent, leading to a binary yes/no to donation after death; it also requires clinicians to engage with the potential donor's family and carry out a nuanced balancing process to decide whether the potential benefits of any proposed donation action outweigh any potential harms, and how this fits best with the strength of the potential donor's desire to donate. This responsibility is not abrogated even after death, as donation actions after death may also not have been acceptable to the patient; hence, a similar balancing process will need to be carried out, even if the risks of harm are no longer the same. To aid clinicians in the UK, an updated framework for considering the acceptability of differing organ donation actions is being developed between professional organisations, and is expected in 2021.

Conclusions

Unlike so many other treatments in medicine, organ donation and transplantation are built upon the altruism of others. This is what makes the two rules for deceased organ donation, outlined in this paper, the DDR and the *consenting donor rule*, fundamental to the legal and ethical practice of this life-saving medical advance. Although the two rules are as old as transplantation itself, they remain only as strong as those willing to follow them.

Declaration of interests

The authors declare that they have no conflicts of interest.

Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.bjae.2021.03.003>.

MCQs

The associated MCQs (to support CME/CPD activity) will be accessible at www.bjaed.org/cme/home by subscribers to *BJA Education*.

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