Organ transplant initiatives: the twilight zone

David P T Price School of Law, De Montfort University, Leicester.

Abstract

Assessments of the acceptability of new transplantation practices require a pinpointing of not only the meaning of death, but also the timing of death. They typically perceive elective ventilation as occurring just prior to death and non-heart-beating donor protocols as operative just after death. However, such practices in fact highlight the general vagueness and ambiguity surrounding these issues in both law and ethics. Supply-side dilemmas in transplantation lend real urgency to this "life or death" debate.

Despite increasing transplantation rates, waiting lists continue to grow for all organs, almost universally. In the UK as of 31.8.96 there were 5,297 patients on the kidney, 305 on the heart and 157 patients on the liver transplant waiting lists. Two procedures which minimise warm ischaemia time affecting the viability of organs for transplantation with clear potential to significantly increase donation rates, "Elective Ventilation" (EV) and "Non-Heart-Beating Donor" (NHBD) protocols, have both, however, been subjected to recent and urgent ethical and legal review.

The new initiatives

In 1988 the Royal Devon and Exeter Hospital became the first British hospital to develop an EV protocol.¹ Patients in deep irreversible coma and believed to be dying imminently of intracranial haemorrhage were transferred to intensive care, with relatives' consent, so that artificial ventilation could be commenced immediately respiratory arrest occurred and until brain (stem) death tests could be satisfied. However, in October 1994, the Health Departments of England and Wales issued guidelines stating that EV for transplantation purposes constituted an unlawful battery – being non-therapeutic and not done in the best interests of the individual.² This mirrored the conclusion of the 1994 King's Fund Institute Report² (which none the less endorsed EV as an *ethically* acceptable practice, as

incidentally have the BMA and the British Transplantation Society), and is probably an accurate perception of the present common law. Although an alternative "not against the interests of the individual" test has been occasionally employed in relation to non-therapeutic procedures performed on minors, such a standard has yet to be legally employed in respect of a mentally incompetent adult person in a similar context. In the 1980s, new NHBD protocols were also implemented, of two distinct types. The pre-eminent example of the first is the University of Pittsburgh Medical Center protocol, under which patients with profound brain damage are gradually removed from ventilatory support, with relatives' or patients' consent, and their organs removed after death is pronounced. Similar protocols have been in operation at the King's College Hospital, Dulwich and in Zurich. The second type involves the perfusion and cooling of organs *in situ*, or whole body cooling, immediately following death and prior to subsequent organ removal. Such protocols are in operation in Britain (for example at Leicester), Italy, France, Spain, Holland, Japan and the United States, and are substantially on the increase worldwide. These are typically temporary measures initiated to allow sufficient time for authorisation for organ donation to be obtained. By contrast with EV, NHBD protocols are by no means new. Not only did they antedate the use of heart-beating donors, they have been in consistent use in countries, for example, Japan, that have yet fully to embrace the concept of brain death.

There has generally been an easy assumption that patients subject to EV are alive whilst NHBDs are dead – although the Pittsburgh protocol has attracted some criticism on this issue. I shall question these assumptions here – the other central ethical issues surrounding these protocols are discussed elsewhere,³ including this journal.⁴ The discussion highlights the vagueness and ambiguity in the legal meaning of death, in this jurisdiction and elsewhere, as well as what criteria/evidence needs to be established in order to determine that death has occurred and when precisely death occurs. As is consistently the case, transplantation practices bring these issues into atypically sharp relief.

Key words

Organ transplants; death; brain death; elective ventilation; non-heart-beating donors.

The legal meaning of death

Commentators who assert that in English law death is brain stem death are rather too dogmatic. Although brain (stem) death, established according to accepted medical criteria, is death in this country and most other countries, English law is vague as to whether death is *only* brain death, as established by the criteria of either brain stem death or the (irreversible) cessation of cardiopulmonary activity, or whether, alternatively, it is *either* brain stem death or the (irreversible) cessation of cardiopulmonary activity?

In three recent cases the courts decided that a brain stem dead patient is dead for legal as well as medical purposes, *Mail Newspapers v Express Newspapers*,⁵ *Re A (A Minor)*⁶ and *Airedale NHS Trust v Bland*.⁷ In the first two cases, the High Court decided simply that the brain stem dead patient was dead. In *Bland* the House of Lords decided that Tony Bland was not dead – his brain stem was still functioning despite his PVS condition. However, although Lord Keith explicitly stated that “In the eyes of the medical world and of the law a person is not clinically dead so long as the brain stem retains its function” (a view of the medical world not wholly borne out by the practices described in this paper!), this was not a central facet of the decision and not binding on future courts (an *obiter dictum*), as he could not have been adjudged dead according to any other criteria as his heart continued to pump and his lungs to carry out gas exchange. In most of the US states (adopting the Uniform Determination of Death Act 1980) and the Australian states and territories, irreversible cardiopulmonary failure is explicitly stipulated by legislation to be an alternative legal standard of death. In Britain this *may* well also be so, despite the absence of any recent authoritative and explicit legal statement to this effect.

The meaning of death

ELECTIVE VENTILATION

By contrast with the majority view across all disciplines, the clinicians who developed the Exeter protocol argue that the process of dying is not prolonged by EV, as the patient is already dead – one is ventilating a corpse. The basic disagreement here might seem to be founded on a dispute as to the meaning of death itself, whereas this is not in fact so, only brain death is in issue – it is not possible to rely on traditional cardiopulmonary criteria when the natural functioning of the heart and lungs is obscured by the intervention of the ventilator. Moreover, the clinicians themselves do not purport to be relying on “cardiopulmonary death”. Riad, from Exeter, has said “The procedure causes no harm to the patient as ventilation is instituted at the time of respiratory arrest *which is the consequence of brain death*. . . . Therefore it is important not to institute EV before respiratory arrest”.⁸ Such a sequence of events is

explicitly referred to in the Memorandum on the Diagnosis of Death attached to *Cadaveric Organs for Transplantation* (1983) issued by the Conference of the Medical Royal Colleges: “In a minority of cases, brain death does not occur as a result of the failure of other organs or systems but as a direct result of severe damage to the brain itself from, perhaps, a head injury or a spontaneous intracranial haemorrhage. Here the order of events is reversed: instead of the failure of such vital functions as heart beat and respiration eventually resulting in brain death, brain death results in the cessation of spontaneous respiration: this is normally followed within minutes by cardiac arrest due to hypoxia. If however oxygenation is maintained by artificial ventilation, the heart beat can continue for some days, and haemoperfusion will for a time be adequate to maintain function in other organs, such as the liver and kidneys”.⁹ Supporters of the Exeter protocol argue that cessation of respiration is (necessary and sufficient) evidence that the patient has *already* succumbed to brain death – the question is whether this is so.

NON-HEART-BEATING DONORS

Under the Pittsburgh protocol, organs are removed immediately the patient is shown to be apnoeic and unresponsive for two minutes to one of three electrocardiographic criteria, ie ventricular fibrillation, electric asystole or electromechanical dissociation.¹⁰ Typically though, the medical literature describing NHBD protocols is less than full and explicit as to *how and when* death is determined according to cardiopulmonary criteria. In Tokyo, cooling *in situ* is commenced “immediately after cardiac arrest”, whilst at King’s College, Dulwich organs are removed “up to 45 minutes after the heart has stopped beating”. Unlike EV, NHBD protocols involve a choice between competing concepts of death, not just varying criteria for the same concept of death. As Mason and McCall Smith state, “If we are to accept the concept of ‘brain death’ as argued below, we should treat the person in irreversible cardiorespiratory failure as dying rather than dead – for the true agonal period in natural death is that which lies between cardiac arrest and cerebral failure”.¹¹ According to this perspective, failures of respiration and heartbeat are relevant only because they will *lead*, in some cases, to death.

The primary reliance under NHBD protocols is upon irreversible loss of cardiopulmonary function as the *standard* of death, not simply as evidence of brain death. It is well known that the brain stem (and *a fortiori* the whole brain) will only cease to function after loss of cardiac function and oxygen deprivation lasting for some minutes – certainly more than the two minutes stipulated by the Pittsburgh protocol. But even assuming that there is an independent alternative cardiopulmonary standard of death, it is not clear that such patients are dead even according to this standard. The primary problem here is the

difficulty in establishing that the cessation of respiration and heartbeat was *irreversible* – which is an explicit and invariable legislative stipulation. For many, two minutes of asystole is insufficient to establish that spontaneous auto-resuscitation will not occur. In addition, the Pittsburgh protocol excludes the possibility of interventions that could restart the heart (artificial resuscitation is withheld by virtue of the joint decision of doctors and relatives).

A nebulous concept

But is irreversibility *properly* a facet of legal or ethical standards of death, and if so, what does it convey? Necessarily, reversibility requires the benefit of some significant degree of hindsight, which such protocols may partially preclude in the quest to preserve the viability of organs for transplantation. However, although reversibility is undoubtedly a nebulous and problematic concept, as has been noted by numerous commentators in this journal, it is not for that, or any other, reason dispensable either legally or ethically. Moreover, the notion of reversibility based upon what is “ethically significant”, as suggested by Tomlinson, is dubious.¹² Our duties to the living may dictate whether someone “will die” but they cannot determine whether a person “is dead” ie whether we *could* have reversed it, not whether we *should* have reversed it. Inevitably irreversibility is relative and linked to time and culture, but this is not to say that death is relative as between individuals of the same culture and at the same relevant time.

Cole argues that the notion of irreversibility is superfluous because it is out of line with the “ordinary concept” of death, which is based on the loss of a *natural* capacity to resume (cardio-pulmonary) function, and that consequently such a notion should not form any part of a legal definition of death.¹³ This is surely implausible, since our lives are supported by all manner of non-natural means, some temporary some permanent. None the less, would it not be plausible instead *to link* the notion of reversibility with the notion of natural functioning? Although we surely would not say that a person was dead simply on account of cardiac arrest when we could restore respiration and circulation by artificial means, we would surely not assert either that all individuals were alive until the point where artificial means could not even cause the lungs to inflate or the blood to circulate? It can be sensibly conceived that a person is dead when the functions of the body are being *wholly driven* by technology, ie such measures are not even *assisting* the natural functioning of the body, either temporarily or permanently. At the point where loss of cardiac and respiratory function produces brain stem death the individual ceases to live regardless of extended mechanical “existence” – there is no integrated functioning of the body, and no consciousness, from that moment.

The point of brain death is therefore the critical point in time whether loss of cardiac function and respiration is an end in itself or only the catalyst for loss of brain function. Catherwood argued in this journal that “Dying is not an irreversible process until that process gets to a point where our available technology cannot help”.¹⁴ In so doing he question-begging in using the word “help”. Helped to do what? If lung functioning can be mechanically sustained even where the patient has suffered brain stem death, is he/she “helped” or is he/she already dead?

Ironically, although NHBD protocols are explicitly stated to be founded on cardiorespiratory criteria, after a certain period of time has elapsed artificial ventilation is applied in many instances as well as cardiac massage. This appears to prove that the cessation was *not* irreversible. However, in fact this procedure implicitly relies on the notion of irreversibility propounded above. If not, such donors are simply not “non-heart-beating” at all! As it is imperative to rely on the death of the brain, the issue is simply what evidence is required to establish that such brain death has occurred. There is no dichotomy between heart-beating and non-heart-beating donors. Cardiopulmonary cessation is evidence of death, not death itself.

The timing of death

ELECTIVE VENTILATION

Riad and Nicholls have said “The dilemma is that there is a difference between the diagnosis of death and the timing of death. We believe we ventilate patients at the moment of death, even though we diagnose death only by formal testing for brain stem death some hours later”.¹⁵ The King’s Fund Report also noted that in this context the *actual* point of death might have been the same (where cessation of respiration precedes brain death and when it occurs as a consequence of brain death), but the point of *confirmation* of death is not – as the electively ventilated patient is not officially confirmed as being dead until two sets of brain stem death tests have been performed. Jones, however, has said “Nor can one escape this dilemma by seeking to differentiate between the diagnosis of death and the timing of death. To say that patients are ventilated ‘at the moment of death, even though we *diagnose* death only by formal testing for brain stem death some hours later’ merely shifts the ground as to the ‘determination’ of death. There must be some agreed criteria for determining the moment of death – that is, the doctors must have grounds for being able to say that ‘this patient is dead’ and this in itself entails a process of diagnosis. It is simply that this diagnosis does not comply with the strict criteria laid down for determining ‘formal’ brain stem death”.¹⁶ The potential dichotomy nevertheless exists between the time of death and the diagnosis/confirmation of

death, although this has no significance in everyday cases. The diagnosis of brain death is in one sense inevitably retrospective, death has already occurred at a point in time which is unknown and unknowable. In the NHBD context, Lynn notes that “Unfortunately, for the proponents of the Pittsburgh protocol, society has never been clear about which point in time . . . will count as the actual time of death. . . . Local practice concerning the time of death to be listed on the death certificate varies when neurologic criteria are used, with some jurisdictions usually using the time at which death was finally able to be declared and others listing the time somewhat earlier when brain function was first documented to have ceased”.¹⁷

Judicial acceptance

We have observed that although there is no definition of death in English law, brain stem death established in accordance with the agreed criteria incorporated in the code of practice of the medical royal colleges has been accepted as establishing legal as well as “medical” death. However, whilst this constitutes judicial acceptance of these tests, it does not necessarily indicate that this is the *sole* criterion for the determination of death in law. But what, if any, other evidence of (brain) death would satisfy a court of law? In *Re A*, A, a nineteen-month-old baby in hospital on a ventilator, was ultimately confirmed by doctors as being brain stem dead after two sets of tests were carried out to confirm this, the first on January 21 and the second on January 22. Johnson J stated: “I have no hesitation at all in holding that A has been dead since Tuesday of last week, January 21”. In other words, the *time* of death was *before* the second sets of tests were performed to confirm lack of brain stem responses. However, the code of practice states that the time of death should be recorded as the time when death was conclusively established and that “Death is only conclusively established when the criteria have been satisfied on two successive occasions”.⁹ It appears therefore that the code was *not* fully adhered to in this instance, nor were the recommendations of the British Paediatric Association, which stipulate that in children older than two months, two sets of tests should be conducted separately by two experienced clinicians 12–24 hours apart.¹⁸ *Re A* illustrates that death *can* be legally declared to have occurred according to brain death criteria *before* two sets of tests have been completed and death has been confirmed. Further, in *R v Malcharek*, *R v Steel* the court thought that the victims were dead according to either cardio-pulmonary criteria or brain stem criteria, despite the fact that two of the brain stem death tests were not performed on one victim and one of the tests was not performed upon the other.¹⁹ Despite certain views to the contrary, it seems that there is

no mandatory legal requirement at present that a person cannot be declared brain (stem) dead unless the recommendations of the report of the medical royal colleges – ie the code of practice – have been complied with in their entirety. The code of practice, although highly influential, does not have the force of law.

Kennedy and Grubb have previously analysed the likely legal position if a patient were declared dead according to brain stem criteria but without the code of practice having been fully adhered to. They believe the answer is contingent upon whether a mistake was made as regards the exclusion of certain pre-conditions (for example, drugs, hypothermia, etc), a failure to perform all the relevant tests, or whether the tests were just not repeated. They are of the opinion that with respect to the first matter the court would simply decide, as a matter of fact, whether the patient was nevertheless dead. On the second issue they state that “We take the view that a court, in the absence of evidence of irresponsible behaviour by the doctor, would be reluctant to find that the patient was not dead at the time asserted”.²⁰ On the latter issue they suggest that if the tests were confirmatory the courts would be likely to find that the death occurred after the completion of those tests on the *first* occasion. The cases cited above appear to bear them out. Confirmation is evidence that death has already occurred, reinforcing the dichotomy between the time of death and the date of recording of death. Indeed, the time of confirmation is capable of manipulation for specific ends and therefore should not be invariably tied to the *time* of death. Although no brain stem death “tests” are seemingly carried out at all prior to EV, a thorough diagnosis of the person’s condition is conducted and many of the same contra-indications for brain stem death are ruled out, for example, reversible causes of coma. There must be some possibility that a court would find that an electively ventilated patient *was* already dead when ventilation was commenced where (i) there was confirmation of the loss of ability for spontaneous respiration and (ii) later performed brain stem death tests proved positive – especially where these were performed almost immediately after the patient was ventilated. However, if one of the concerns is that EV protocols may lead to patients being induced into a PVS state, then certainty regarding the moment of death seems rather dubious – although currently we do not know how great this risk is or whether it is even a true risk at all, because of the moratorium on EV itself.

NON-HEART-BEATING DONORS

I have argued that death is only brain death but that in any event the important point in time under *any* standard of death is the point of brain stem death, as only then would cardiorespiratory failure be irreversible. Where brain death *follows* cardiorespiratory failure a period of time must be agreed upon beyond

which it is considered that the brain stem cannot have survived. A consensus apparently developed at a recent symposium of transplantation experts in Maastricht, that at least ten minutes should have elapsed without cardiopulmonary function before a potential NHBD is pronounced dead.²¹ The consultants to the President's Commission incidentally also advised that at least ten minutes of proven lack of circulation to the brain was necessary.²²

Conclusion

Just as currently brain death is partially linked to the notion of the biological death of the organism, and not just loss of personhood, and a judgment needs to be made as to the extent of that biological loss which is compatible with the notion of death, so society must be more decisive as to the level of confidence required to satisfy itself that death has occurred. This in turn requires an *a priori* judgment as to the meaning or definition of death itself, which in its turn dictates the framework for the development of criteria for ascertainment of death. In this connection it is of interest that the Royal College of Physicians recently agreed the following definition of death: "The irreversible loss of the capacity for consciousness combined with irreversible loss of the capacity to breathe", and stated that "brain stem death is equivalent to the death of the individual".²³ Pallis is correct to assert that all death is, and always has been, brain death.²⁴ There is an urgent consequential need for parliament to legislate a definition of death in English law to this effect – this should not be left by default to the judges to develop. United States and Australian state statutes with dual, disjunctive concepts of death mislead and suggest, as many critics have argued, that death means different things in different contexts. It is essential that no perception develop generally in society that the notion of death is being manipulated solely in the transplant context. The detrimental consequences of such a perception would hugely outweigh any short-term benefit to society and to those awaiting organs for transplantation. At the same time, the dichotomy between the diagnosis of death and the time of death requires clarification. If a patient is not actually dead until two sets of brain stem death tests are carried out, as the code suggests, then the patient is still alive up until that point. No procedures should therefore be carried out which are not in the patient's best interests, such as those designed solely to preserve the viability and quality of a potential transplant organ. This would fall foul of the same proscription as EV, ie that it constitutes an unlawful battery. If the second set of tests are confirmatory instead, then such procedures may be permissible, because the individual is dead.

The criteria needed to establish brain death will still inevitably include the irreversible cessation of cardiopulmonary function – this is an integral feature of medically accepted criteria, employed in virtually

all deaths occurring outside hospital. The necessary period of cessation should reflect the consensus within the medical profession (not just the transplant community) and attract public confidence. The criteria (including any agreed time period) might be published in a revised and discrete code dealing with the determination of death in general, applicable to physicians in the community as well as to hospital doctors involved in transplantation practices or otherwise. The latter scenario may attract the attention of commentators but is a good deal more public and transparent than the former.

David Price is Principal Lecturer in Law at the De Montfort University, Leicester, teaching and researching in medical and criminal law. He is Co-Director of the EUROTOLD research project on organ transplantation, funded by the European Commission. Address for readers' correspondence: School of Law, De Montfort University, The Gateway, Leicester, LE1 9BH.

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