Not Dead Yet: Controlled Non-Heart Beating Organ Donation, Consent, and the Dead Donor Rule

Dr D Gardiner MBBS MBioeth FANZCA Consultant in Critical Care and Anaesthesia Adult Intensive Care Unit Queen's Medical Centre Campus, Nottingham, University Hospitals, Derby Road Nottingham NG7 2UH United Kingdom

Dr. Robert Sparrow. BA (Hons) PhD. School of Philosophy and Bioethics Faculty of Arts Monash University Victoria 3800 Australia

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Introduction

The emergence of controlled, Maastricht Category III, Non-Heart Beating organ Donation (NHBD) programs ¹ has the potential to greatly increase the supply of donor solid organs by increasing the number of potential donors. Category III donation involves unconscious and dying intensive care patients whose organs become available for transplant after life sustaining treatments are withdrawn, usually on grounds of futility. The shortfall in organs from Heart Beating organ Donation (HBD)² following brain death has prompted a surge of interest in NHBD. ³⁴⁵ In a recent editorial, the British Medical Journal described NHBD as representing "a challenge which the medical profession has to take up."

Criticism of controlled NHBD programs has mostly focussed on the criteria used for determining death, the potential for conflict of interests to arise for the treating physician in managing the dying patient, and the possibility that clinicians might violate the Dead Donor Rule (DDR) by hastening the death of the patient through the administration of drugs or interventions in treatment. 78910111213 We believe there is a more fundamental ethical concern with controlled NHBD. 14 We hold that the DDR is violated not just by donation practices which bring about the death of the patient but whenever clinicians treat the living donor as though they were dead. In controlled NHBD, because of the need for haste in salvaging organs before lack of circulation of oxygenated blood irreversibly damages them, there is a strong incentive to initiate surgical and/or institutional procedures to facilitate donation *before* death occurs. We argue that these medical procedures, which "treat" one patient for the benefit of another, represent a significant departure from the ethical practice of medicine. That the patient is likely to remain unaware of these interventions does not change this; the idea that it

does, we suggest, relies on a surreptitious—and false!—claim that the patient is, for all intents and purposes, dead already. Controlled NHBD will therefore usually require violating the DDR.

The conclusion that NHBD will often violate the DDR is, perhaps, not as damning of the procedure as first appears, given recent criticism of the DDR by a number of eminent medical ethicists. It is possible that pre-mortem interventions might be justified with reference to the patient's—or an appropriate surrogate decision maker's—consent to organ donation. However, reminding ourselves that the patients involved in NHBD are "not dead yet" should draw our attention to significant implications of this fact for the level and nature of consent that is appropriate before these procedures can be undertaken ethically. Moreover, if the cost of embracing controlled NHBD is abandoning the DDR we believe that ethical debate about NHBD should be conducted in full awareness of this fact and not be foreclosed by any attempts to redefine death, or by naive appeals to utilitarian considerations.

I - Non-Heart Beating Organ Donation: Background and Practice

Unsurprisingly, when transplantation first became a viable option, the American Medical Association (AMA) insisted that vital organs should only be harvested from patients who were already dead. The "Dead Donor Rule" requires that the patient be dead—and be declared dead by a physician without any possible conflict of interest—before vital organs are harvested for donation. Prior to the acceptance of brain death, cadaveric donations were from patients who had been declared dead by traditional cardio-pulmonary criteria. The damage suffered by organs deprived of the circulation of oxygenated blood when the donor's heart stopped beating was a significant barrier to successful transplantation from such donors. However, the recognition of brain death as a criterion of death made it possible to source organs from persons who could be declared legally dead even though their hearts were still beating.

Recently, because of a shortage of organs for transplantation, there has been renewed interest in NHBD. Table 1 sets out the differences between controlled NHBD and HBD.

Table 1: Cadaveric Organ Donation Today

| Types of Solid Organ | 'Controlled' Non-heart | Heart beating |
|-------------------------|---------------------------|---|
| Cadaveric Donations | beating donation | donation |
| (UK | (NHBD) | (HBD) |
| Nomenclature) | | |
| (Alternative US and | 'Controlled' Donation | Donation after brain |
| Australian | after Cardiac Death | death |
| Nomenclature) | (DCD) | |
| UK criteria used to | Traditional Cardio- | Brain Stem Death |
| diagnose death. | Pulmonary Criteria: the | Criteria: irreversible |
| | irreversible cessation of | cessation of brain stem |
| | cardiac and respiratory | function as manifested |
| | activity. | by irreversible loss of consciousness and the |
| | | irreversible loss of the |
| | | ability to breathe. 18 |
| | | donney to oreathe. |
| State of the patient at | Alive | Dead |
| the time of the | | |
| discontinuing of | | |
| mechanical ventilation | | |
| and circulatory | | |
| support. | | |
| The heart's activity at | Ceased | Beating |
| the time of the | | |
| declaration of death. | | |
| Usual time frame from | Less than 15 minutes | A few hours, often |
| the declaration of | | greater than four |
| death to the time of | | |
| surgical incision | | |
| commencing the organ | | |
| retrieval. | | |
| Organ Warm | Practical UK minimum | < 1 minute |
| Ischaemic Time | 15 minutes, often longer | |
| | | |
| Common organs that | Kidneys | Kidneys |

| can be used for | Liver | Liver |
|-----------------|----------|-------------|
| transplantation | Lung | Lung |
| _ | Pancreas | Pancreas |
| | | Heart |
| | | Small Bowel |

Two features of this comparison are especially important in relation to donation practices in NHBD. Firstly, controlled non-heart beating donors have their mechanical ventilation and circulatory support withdrawn whilst they are still alive, whereas in HBD discontinuation occurs after the declaration of death. Secondly, NHBD involves greatly increased warm ischaemic time compared to HBD, since cardio-pulmonary failure must precede organ donation.¹⁹

Attempts to improve the outcomes of transplants from NHB donors therefore, for the most part, focus on reducing the length and degree of warm ischaemic time. These attempts can be divided into two broad categories: those procedures that are initiated before the patient's heart has stopped beating and death has been declared and those that take place post-mortem.²⁰

A number of means may be used to minimise warm ischaemic time after the patient's heart has stopped beating. Most obviously, the time between this moment and the cold perfusion of organs may be reduced by minimising the time between cessation of blood circulation and the declaration of death. This is achieved by using cardio-pulmonary death criteria that require that the pulse be absent for only a very short period of time before death can be declared. Once death has been declared, intravenous medications to reduce damage to organs may be administered or the organs perfused with cold fluids while still in the body via a femoral catheter. Rarely, external heart compression and extracorporeal oxygenation may be initiated, in order to maintain organ function, right up to the time of organ retrieval.

The desire to reduce warm ischaemic damage to the donor organs has led to a much-compacted time frame for determining death in NHBD, which may, in some circumstances, introduce significant uncertainty in the diagnosis of death. However, this is not our main concern here, which is the nature and ethical significance of those interventions that occur before death.

The nature of *pre*-mortem interventions in NHBD varies between nations.

In the United States of America (USA) pre-mortem intervention is the norm. Life-sustaining treatment is usually withdrawn in the operating theatre instead of the intensive care unit in order to minimise the time between the declaration of death and organ retrieval. In order to enhance organ viability, intravenous medications may be administered, and/or the patient cannulated, whilst the patient is still alive so that the organs can be perfused with appropriate preserving fluids immediately after death is declared.²⁹

The UK Intensive Care Society (ICS) rejects the USA practice for pre-mortem physical intervention.

The ICS guidelines for NHBD insist that once a decision to withdraw life-sustaining care has been reached:

It is inappropriate to escalate current treatment, add new therapies (e.g. inotropes, heparin, hormone replacement) or to undertake invasive interventions (e.g. vascular cannulation before death for cold perfusion) to improve organ viability ... Withdrawal of active treatment should usually take place within the critical care unit. In exceptional circumstances treatment may be withdrawn within the theatre complex (e.g. an anaesthetic room, recovery area). This should be undertaken only as a way of meeting the patient's and relatives' wish to donate organs and not simply as a means of reducing warm ischaemic time. ³⁰

The justification for this policy is not stated in the ICS guidelines but it is likely to be that premortem physical interventions are problematic because they offer no medical benefit to the patient—a view with which we are obviously in sympathy.³¹

Pre-mortem interventions in the UK are more subtle and take the form of organisational and attitudinal changes to the dying process. In order to reduce warm ischaemic time in controlled NHBD, withdrawal of life-sustaining treatment in the ICU will typically not commence until preparations for donation have been completed and the surgical team are in readiness. The timing of the withdrawal of treatment is chosen to maximise organ viability and not for the benefit of the donor. Similarly, the preferred method of mechanical ventilation discontinuation is to remove the breathing tube from the patient, a method known as terminal extubation, in order to promote a rapid demise, despite the fact that this increases the risk that the patients' relatives will be distressed by the process of their dying.

II – The ethical significance of pre-mortem interventions

Most discussions of the implications of the DDR interpret this rule as prohibiting interventions that bring about the death of the patient in order to harvest a vital organ and in particular those interventions that might *bring about* the death of the patient *by removing* a vital organ. That is to say, they interpret the DDR as prohibiting the *killing* of patients in order to harvest their organs. ³²³³³⁴ We believe that this is an artificially narrow reading of the DDR. In an important discussion of the DDR, Arnold and Youngner distinguished between two components of the rule, a prohibition on *killing* and a prohibition on *using living patients* solely as a means to an end. This second component of the DDR, which should be understood as affirming the respect due to living persons by demanding that donors must be dead *before* their organs can be removed to advance the ends of others, ³⁵³⁶ is equally as important as the first. Thus, for instance, in a recent New England Journal of Medicine "Perspective Roundtable" on "Organ Donation after Cardiac Death", Arthur Caplan answers the question "What is the dead donor rule?" by saying:

The dead donor rule says we take organs, vital organs, only from those who've been clearly, unequivocally pronounced dead. *So nothing will happen in terms of procurement, requests, anything, until you've got a team that establishes death* [our emphasis].³⁷

Similarly, we hold that the DDR is breached whenever procedures to harvest vital organs are initiated while the patient is still alive.

In practice, controlled NHBD will usually violate the DDR. The pre-mortem procedures that are initiated to minimise warm ischaemic time in NHBD, such as cannulation, and organisational and attitudinal changes that involve the patient being viewed primarily as an organ donor rather than an unconscious intensive care patient, treat a living person as a means to the ends of others. Importantly, these breaches of the DDR are necessary to maximise the chance of successful NHBD, whereas in HBD all donation preparation can await the declaration of death.

It might be objected that we have overstated the significance of the pre-mortem interventions involved in NHBD. In the UK, at least, the changes in the treatment of potential donors involve only organisational and administrative matters, which arguably do not impinge on the welfare of the patient. Even the more robust physical interventions practised in the USA have no impact on the subjective experience of the patient, who is unconscious. It is our impression that the claim that the changes in the care of patients are trivial is the most common response from those working in donation to criticism of controlled NHBD programs.³⁸

Yet, ethical medical practice consists in not just what patients experience but how they are treated—even if they are absent or unconscious. As both Kantian and virtue ethics insist, attitudes can be morally significant.

One way of bringing out the troubling nature of the attitudinal changes involved in NHBD is to imagine the logical extension of the pre-mortem interventions that are currently employed to facilitate organ salvage. With appropriate anaesthesia, it would be possible to reduce warm ischaemia even further by surgical exposing the organs to be salvaged before life support was withdrawn. As long as the patient's heart stopped beating as the result of life-sustaining treatment being withdrawn rather than as a result of the preparations for donation, then this procedure would be compatible with an interpretation of the DDR that only prohibited *killing* the patient. Yet it is clear that, in this scenario, we would be flagrantly violating the ordinary standards of ethical medical practice. Moreover, the real source of the violation here is the fact that we are treating a living patient as though they were dead rather than the details of the particular surgery. This shift in attitude towards the patient is also characteristic of current practices of pre-mortem intervention to facilitate NHBD; it is for this reason that we believe these practices violate the DDR.

III – Consent and the best interests of the patient

That controlled NHBD will usually violate the DDR need not be a decisive objection to it. A number of authorities have previously canvassed the idea that we should abandon the DDR, in part because of the barrier it poses to organ donation. ³⁹⁴⁰⁴¹⁴²⁴³⁴⁴⁴⁵ Abandoning the DDR would shift the burden of establishing that a particular organ salvage is ethically permissible to the question of consent.

We are prepared to entertain the possibility that pre-mortem interventions in the care of a controlled NHB donor may be legitimate if we have informed consent to such interventions from the patient or an appropriate surrogate: that is, consent—either current or prior—that is informed, voluntary, and provided by a competent agent. However, an unconscious intensive care patient has no current capacity to consent to such procedures. In the absence of prior—or surrogate—consent, that means that doctors must act in a patient's best interest.

All of the UK policies we reviewed for this paper allow for controlled NHBD to commence on the absence of objections from the family and/or registration on the Organ Donor Register (ODR). Indeed, under the UK Human Tissue Act (HTA) presence on the ODR is defined as legal consent for organ donation. The use of this standard in NHBD means that the "consent" process for NHBD is exactly the same as used in HBD—another indication that controlled NHBD treats the potential NHB donor as effectively dead already.

More importantly, it is clear that the process of registration on the ODR falls well short of that required to establish informed consent.⁵¹ The educational materials associated with the ODR consist in information designed to encourage donation, with no mention of possible negative consequences of participation in donation; nor is there an opportunity for potential donors to have their individual questions about donation answered. Given these limitations of the ODR, registration should not be held to constitute informed consent to pre-mortem interventions to facilitate NHBD.⁵²

In countries that allow for surrogate consent, there may well be more opportunity to gain appropriate consent for NHBD. A full discussion of the role of surrogate consent in the treatment of incompetent patients is beyond the scope of this article. However, we would note that surrogate decision makers are typically held to be under the obligation to make decisions they regard are in the patient's best interest and accordance to that person's prior expressed views. Allowing surrogates to consent to treatments that have no medical benefit for the patient would involve a significant shift in the role of such decision makers, which should be (very) ethically controversial. A possible exception would be where the patient has previously expressed strong views about their willingness to undergo particular medical procedures. However, the mere fact of registration on the ODR is insufficient evidence of the existence of such views.

In the absence of clearly expressed prior consent to pre-mortem interventions might there nevertheless be a case to be made that, where patients have registered on the ODR, such interventions are in their best interest? If we adopt an account of well-being that focuses on the satisfaction of an agent's preferences then it may be in their interests to undergo pre-mortem procedures to facilitate donation if their preference was to donate. As Dr DeVita said in challenge to the known UK objection to pre-mortem intervention at the 3rd International Meeting on Transplantation from Non-Heart Beating Donors in London, "If you [the organ donor] do want to donate organs you don't want to donate bad organs." ⁵³

However, there are number of reasons to be cautious about this approach as a solution to the ethical problems involved in NHBD. First, preference satisfaction accounts of well-being are controversial and subject to a number of well-known objections. 545556 Second, there is a certain amount of intellectual strain involved in thinking of pre-mortem interventions in the care of a patient designed to facilitate NHBD as motivated by a concern for the best interests of the donor. They are more naturally understood as driven by a concern for the best interests of potential organ recipients. This is not to say that donation and the procedures necessary to facilitate it might not also be in the donor's best interests. However, the strong interests of other parties in the donation process lends weight to the suspicion that the account of well-being supposed here has been chosen for the support it lends to NHBD rather than on its own merits. Third, even on a preference satisfaction account of well-being it is unlikely that the satisfaction of a patient's every preference will be in their best interests. Instead, the extent of the satisfaction of their strong or considered preferences will determine a patient's wellbeing. Yet, as we observed above, registration on the ODR is an unreliable indicator that donors have a strong preference to undergo particular procedures. Moreover, fourth, there are good reasons to believe that many patients might object to interventions that treat them as though they were already dead and that may involve assaults on their physical integrity and dignity and/or prove

psychologically distressing to their loved ones. In the absence of compelling evidence that a particular patient had strong preferences to allow intervention in the dying process in order to facilitate donation, then, it is inappropriate to judge it to be in a patient's best interests to undergo procedures that are more naturally described as benefiting other people.

Of course, if the salvage of vital organs while the patient is still alive can be justified by securing consent then the question arises why we should continue to put such stock in the distinction between withdrawing treatment and actively euthanising patients? If we are prepared to violate the DDR by beginning the removal of vital organs before death occurs, as long as we have appropriate consent, should we not also be prepared to violate it by killing the patient in the course of doing so—or, indeed, in order to do so? Posing the question in this blunt form highlights the challenge that controlled NHBD poses to the ethical practice of organ salvage and donation.

IV - Redefine Death?

An alternative response to concerns about violations of the DDR in the course of controlled NHBD is to claim that the unconscious and dying intensive care patient *is,* in all relevant senses, dead already and therefore that it is entirely appropriate for them to be treated in the same way as those who are brain dead.⁵⁷ If we are prepared to distinguish between the death of the person —the centre of conscious experience that is worthy of moral regard—and the death of the human organism then we may be able to claim that sometimes while the organism is still alive the person may be dead. If personhood is any of the following: perceiving oneself as existing over time, rationality, possession of preferences, or goal setting; then it might be argued that the unconscious and dying intensive care patient has died prior to donation.⁵⁸⁵⁹ According to this line of thought, controlled NHBD *does* satisfy the DDR after all.

Whether this distinction is a plausible one and the consequences for medical practice of adopting criteria of death that focused on "death of the person" are questions too large for us to settle here. ⁶⁰ In this context it will suffice to note just how radical a change in our notion of death such a move would involve. 61 As a number of philosophers have argued, infants are not persons in the sense outlined above, as they lack both future regarding preferences and a sense of themselves as persisting through time. 626364 Similarly, on this account, many individuals at the end of life, particularly those suffering advanced dementia, will be dead for long periods of time before their bodies expire. Indeed, the "person" may have "died", albeit perhaps only temporarily, whenever a patient is unconscious. Insisting that death involves the irreversible loss of the capacities listed above does not entirely resolve these anomalies (for instance, it cannot explain why it would be directly wrong to kill an infant before they had formulated the desire to stay alive) and has the further consequence of rendering the answer to the question as to whether a patient is dead or not hostage to future events. As Peter Singer has argued, this "revised" concept of death, shaped to fit a very particular—if widely shared—set of philosophical commitments, is so implausible an account of *death* that we can only account for it being contemplated at all as a consequence of the desire to make more organs available for transplant, possibly because of utilitarian concerns of the sort we consider below. 6566 Short of this radical revision of our concept of death, NHBD patients are clearly still alive until they have suffered brain death or their hearts have stopped beating.

V - The utilitarian case for NHBD

There is of course a utilitarian justification for controlled NHBD programmes, which argues that any negative impacts of violations of the DDR or of breaches of consent are outweighed by the great benefits provided to the recipients of organs from these programs. We suspect that a vivid awareness of the situation of those awaiting the availability of organs for transplantation, along with the belief

that any harms to the donors involved in NHBD, if not trivial, are not of the same order as those confronting potential recipients, serves to justify NHBD programs in the eyes of many of those involved in them.

However, this utilitarian argument is—as is so often the case with utilitarian arguments—much too powerful and would justify policies that are clearly unethical by current standards. For example, John Harris's notorious "survival lottery", wherein the organs of randomly selected healthy persons would be confiscated and redistributed to the needy sick, can be justified on utilitarian grounds. ⁶⁷ The ease with which repugnant conclusions can be justified using utilitarian arguments suggests that we should be extremely cautious about abandoning long-held principles of ethical medicine, such as respect for patient autonomy and concern for the best interests of each and every individual under our care, in response to the demands of a utilitarian calculus. ⁶⁸

If proponents of NHBD wish to justify pre-mortem interventions without consent in NHBD with reference to a utilitarian calculus then it would be best if this were done explicitly and not (mis)represented as a claim about the nature or significance of death. Society would then be able to make a clear choice about whether or not to permit such interventions. ⁶⁹ We believe that an honest acknowledgement of the fact that, where it involves pre-mortem interventions, controlled NHBD involves taking organs from living patients and must be justified—if, indeed, it *can* be justified—by reference to the consent of the donor is an essential first step in the debate about the ethics of these practices.

VII - Conclusion

Controlled NHBD offers tremendous opportunities: it also offers new ethical challenges. In practice, NHBD will usually violate the DDR by beginning the procedures to remove vital organs well before

the patient is dead. Abandoning the DDR shifts the burden of the argument for ethical NHBD onto the question of consent. We argue that the appropriate consent for medical procedures to be carried out while the patient is still alive is informed consent and that registration on an organ donor registry is itself insufficient to justify pre-mortem interventions in the care of NHBD patients. There may be some scope for ethical pre-mortem intervention in NHB donation where prior consent has been given or where surrogates are capable of drawing on reliable knowledge of a potential donors' own preferences. However, again, the mere fact of registration for organ donation should not be taken to establish the existence of a preference to undergo pre-mortem interventions. The argument that pre-mortem procedures to facilitate donation are in a patient's best interest is tendentious and, in practice, is also likely to founder on difficulties in demonstrating that NHB donors had strong preferences to undergo such procedures. While there may be a utilitarian case to be made for NHBD, any such argument is likely to suffer from the familiar failings of utilitarian arguments: that they sanction the instrumentalisation of persons and can be used to justify intuitively repugnant policies. It is, therefore, our conclusion that current moves towards more widespread NHBD can only be justified if we are prepared to abandon the Dead Donor Rule.

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Endnotes

¹ In the US nomenclature, "Donation after Cardiac Death" (DCD) programs.

² In the US nomenclature, "Donation after Brain Death" (DBD) programs.

³ Bell MDD. Non-heart beating organ donation: old procurement strategy—new ethical problems. *Journal of Medical Ethics* 2003;29(3):176–81.

- ⁴ Steinbrook R. Organ Donation after Cardiac Death. New England Journal of Medicine 2007;357(3):209–13.
- ⁵ Bernat JL, D'Alessandro AM, Port FK, Bleck TP, Heard SO, Medina J, et al. Report of a National Conference on Donation after Cardiac Death. *American Journal of Transplantation* 2006;6:281–91.
- ⁶ White SA, Prasad KR. Liver transplantation from non-heart beating donors: a promising way to increase the supply of organs. *British Medical Journal* 2006;332:377.
- ⁷ See note 3, Bell 2003:176–81.
- ⁸ See note 4, Steinbrook 2007:209–13.
- ⁹ Whetstine L, Bowman K, Hawryluck L. Pro/con ethics debate: is nonheart-beating organ donation ethically acceptable? *Critical Care* 2002;6(3):192–5.
- ¹⁰ Gardiner D, Riley B. Non-heart-beating organ donation—solution or a step too far? *Anaesthesia* 2007;62:431–3.
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- ¹² Zamperetti N, Bellomo R, Ronco C. Defining death in non-heart beating organ donors. *Journal of Medical Ethics* 2003;29:182–5.
- ¹³ Youngner SJ, Arnold RM. Ethical, psychological, and public policy implications of procuring organs from non-heart-beating cadaver donors. *Journal of the American Medical Association* 1993;269(21):2769–74.
- ¹⁴ This article is primarily a critique of current UK controlled NHBD practice. However, we also hope our discussion will be relevant to debates about NHBD in other jurisdictions.
- ¹⁵ See note 13, Youngner, Arnold 1993:2771.
- ¹⁶ Judicial Council of the American Medical Association. Ethical guidelines for organ transplantation. *Journal of the American Medical Association* 1968 Aug 5;205(6):341–2, at 342, point 3.
- ¹⁷ Arnold RM, Youngner SJ. The dead donor rule: should we stretch it, bend it, or abandon it? *Kennedy Institute of Ethics Journal* 1993;3(2):263–78.
- ¹⁸ The relative merits of *whole* brain versus brain *stem* criteria of death is something we will avoid exploring as it is orthogonal to the argument of this paper.
- ¹⁹ The time period from when blood perfusion is inadequate to meet the tissue's needs to when the organ is perfused with cold fluids is known as the "warm ischaemic" time. The time period from cold perfusion to transplantation into the recipient is known as "cold ischaemic" time. See note 5, Bernat, D'Alessandro, Port, Bleck, Heard, Medina, et al. 2006:281–91 for discussion of each of these.
- ²⁰ See note 13, Youngner, Arnold 1993:2769–74.
- ²¹ The current recommendations to diagnose death by cardio-pulmonary grounds are a minimum of two minutes of pulselessness, as documented by an absent arterial line waveform, in the USA versus a minimum of 5 minutes of asystole, as documented by the absence of electrical activity by an electrocardiogram in the UK.
- ²² See note 10, Gardiner, Riley 2007:431–3.
- ²³ See note 3, Bell 2003:176–81.
- ²⁴ See note 5, Bernat, D'Alessandro, Port, Bleck, Heard, Medina, et al. 2006:281–91.
- ²⁵ This is of considerable concern in potentially increasing the number of cases of Lazarus syndrome (autoresuscitation). Theoretically, it also might mean that brain function is re-established. These possibilities in turn place significant pressure on the idea that these patients are dead by either brain or cardiac death criteria, which refer to the *irreversible* loss of function of these organs.
- ²⁶ See note 3, Bell 2003:176–81.
- ²⁷ See note 10, Gardiner, Riley 2007:431–3.

- ²⁸ See note 9, Whetstine, Bowman, Hawryluck 2002:192–5.
- ²⁹ See note 5, Bernat, D'Alessandro, Port, Bleck, Heard, Medina, et al. 2006:281–91.
- ³⁰ United Kingdom Intensive Care Society Working Group on Organ and Tissue Donation. *Guidelines for Adult Organ and Tissue Donation*. England: United Kingdom Intensive Care Society; 2004:46–7 [cited 2008 May 20]. Available from: http://www.ics.ac.uk/icmprof/downloads/Organ%20&%20Tissue%20Donation.pdf.
- ³¹ One of the key principles of ethical donation practice as formulated in the original advice on this matter from the Judicial Council of the American Medical Association is that "A prospective organ transplant offers no justification for relaxation of the usual standards of medical care." See note 16, Judicial Council of the American Medical Association 1968:342, point 2.
- ³² See note 11, Robertson 1999:6–14.
- ³³ See note 4, Steinbrook 2007:209–13.
- ³⁴ See note 5, Bernat, D'Alessandro, Port, Bleck, Heard, Medina, et al. 2006:281.
- ³⁵ Campbell CS. Harvesting the living?: separating "brain death" and organ transplantation. *Kennedy Institute of Ethics Journal* 2004;14(3):301–18, at p.314.
- ³⁶ See note 17, Arnold, Younger 1993:264–5.
- ³⁷ New England Journal of Medicine. Perspective Roundtable on Organ Donation after Cardiac Death [cited 2009 April 20]. Available from http://content.nejm.org/cgi/data/359/7/669/DC1/1.
- ³⁸ One of the authors (Gardiner) is an intensive care specialist and has heard this opinion expressed a number of times in conversation at NHBD conferences.
- ³⁹ Fost N. Reconsidering the dead donor rule: is it important that organ donors be dead? *Kennedy Institute of Ethics Journal* 2004;14(3):249–60.
- ⁴⁰ See note 11, Robertson 1999:6–14.
- ⁴¹ Zamperetti N, Bellomo R, Defanti CA, Latronico N. Irreversible apnoeic coma 35 years later. Towards a more rigorous definition of brain death. *Intensive Care Medicine* 2004;30:1715–22.
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- ⁴³ Truog RD, Robinson WM. Role of brain death and the dead-donor rule in the ethics of organ transplantation. *Critical Care Medicine* 2003;31(9):2391–6.
- ⁴⁴ Youngner SJ, Arnold RM. Philosophical debates about the definition of death: who cares? *The Journal of Medicine and Philosophy* 2001;26(5):527–37.
- ⁴⁵ See note 17, Arnold, Youngner 1993:263–78.
- ⁴⁶ See note 13, Youngner, Arnold 1993:2771.
- ⁴⁷ See note 11, Robertson 1999:6–14.
- ⁴⁸ See note 5, Bernat, D'Alessandro, Port, Bleck, Heard, Medina, et al. 2006:281–91.
- ⁴⁹ Human Tissue Authority. *Code of Practice—Consent: Code 1.* UK: Human Tissue Authority; 2006 [cited 2008 May 20]. Available from: http://www.hta.gov.uk/_db/_documents/2006-07-04 Approved by Parliament Code of Practice 1 Consent.pdf.
- ⁵⁰ Human Tissue Authority. *Code of Practice—Donation of Organs, tissue and cells for transplantation: Code* 2. UK: Human Tissue Authority; 2006 [cited 2008 May 20]. Available from: http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_2_-Donation of Solid Organs 200607133233.pdf.
- ⁵¹ The move in the UK to secure 'Family Lack of Objection' rather than consent suggest that the UK is moving away from a concern for consent to donation even for HBD.

- ⁵² Gardiner D. An unethical marriage—the Human Tissue Act and the UK NHS Organ Donor Register. *Journal of the Intensive Care Society* 2007;8(2):42–3.
- ⁵³ DeVita MA. Changing practice in NHBD. Paper presented at 3rd International Meeting on Transplantation from Non-heart Beating Donors, London, 2006 May 12.
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