

Defining death in non-heart beating organ donors

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Protocols for retrieving vital organs in consenting patients in cardiovascular arrest (non-heart beating donors, NHBD) rest on the assumptions that irreversible asystole a) identifies the instant of biological death, and b) is clinically assessable at the time when retrieval of vital organs is possible. Unfortunately both assumptions are flawed. We argue that traditional life/death definitions could be actually inadequate to represent the reality of dying under intensive support, and we suggest redefining NHBD protocols on moral, social, and anthropological criteria, admitting that irreversible (however defined) asystole can only equate a clinically determinable point of no return in the process of dying, where organ retrieval can be morally and socially accepted in previously consenting patients.

Judgments on death seem to be cold, hard, scientific facts. That, no doubt, is why they are easier to accept than their alternative, the making of fallible value judgments about the worth of lives.¹

A determination of death is a legal determination that a collection of living cells is no longer entitled to the rights granted to human beings, rather than a scientific or medical determination that all biological life has ended. ... The question is, at its core, not a medical question but a moral or religious one.²

Non-heart beating organ donors (NHBD) were the first source for organ transplantation.^{3–4} After the definition of brain death (BD) in 1968,³ heart beating brain dead donors (HBDD) became the major source of transplantable organs. In 1993, a NHBD protocol was started in Pittsburgh in an effort to increase the number of available organs. The practice of NHBD is now increasing³ and protocols are currently applied with good quantitative⁵ and qualitative results.³ None the less, HBDD remain the major source of transplanted organs worldwide.

The unique position of the brain in the definition of death was officially recognised in 1981:

The heart and lungs are not important as basic prerequisites to continue life but rather because the irreversible cessation of their functions shows that the brain had ceased functioning.⁷

In this sense, the Uniform Determination of Death Act (UDDA) acknowledged that:

An individual who has sustained either irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain, including the brain stem, is dead.⁸

Both the NHBD and the HBDD protocols rest upon the “dead donor rule”: patients must be dead before organ retrieval and death must be neither caused nor hastened by the retrieval.

Life and death in this context are intended in a strict biological sense (as distinct from anthropological, psychological, and sociological death): the death of a human being is the same as the death of an animal or plant.

The above paradigm might seem ethically, morally, and practically very straightforward. It is not. Actually, NHBD protocols raise major ethical concerns regarding the definition of the donors' vital status. In this essay, we will argue that clinical criteria can only certify the clinical condition of asystole, whose equivalence to “life” or “death” cannot be defined by medicine alone. This doesn't mean that NHBD are still alive at the moment of organ retrieval, but simply that medicine alone cannot demonstrate that they are surely dead. In this sense, in our view, NHBD protocols have to be re-established on moral, social, and anthropologic criteria, which must be openly formulated, discussed, and accepted.

We suggest that reformulating the policy of organ retrieval from NHBD, taking these issues into account, is in the best interests of donors, their families, recipients, society as a whole, and the long term future of organ transplantation in general.

CAN MEDICINE DIAGNOSE THE STATUS OF NHBD?

Two NHBD subsets exist: the **controlled** (organ procurement following a planned withdrawal of futile or excessively burdensome artificial life support) and the **uncontrolled** (retrieval following unsuccessful cardiopulmonary resuscitation).

The most important difference is how the UDDA term of “irreversible” relates to cardiocirculatory function: in the latter subset, “irreversible” means *in spite of any possible intervention* (a strong sense), while in the former it means *spontaneously* irreversible (the weakest possible sense) because, for such patients, forgoing of life support is intended as the most appropriate action:

It is legitimate to declare death when it has been established: (1) that circulation and respiration have ceased; (2) that these functions will not resume spontaneously, and (3) that the physician should not resuscitate. ... That the physician should not resuscitate—even were this possible—is known by the fact that all the patients in

question or their proxies made a decision to withdraw life support because it was deemed excessively burdensome or futile.⁹

The two subsets converge in the fact that organs are harvested as soon as possible after asystole. The period of time between asystole and retrieval is, however, variable. Recently, the Institute of Medicine (IOM) surveyed the NHBD protocols.¹⁰ Twenty nine out of 63 organ procurement organisations answered: only half of them mentioned a specific waiting time (one to five minutes in 12 organisations, no wait after asystole in the other ones). The IOM recommends a five minute interval. Indeed, NHBD protocols continue to be extensively debated.^{9 11–17}

A recent paper published by the ethics committee of the Society of Critical Care Medicine³ reports a review (Youngner *et al*¹⁸) which demonstrates that none of 108 patients with apnoea, asystole, and unresponsiveness for at least two minutes recovered spontaneously. It also points out that non-potential organ donors in the intensive care unit (ICU) are often certified dead after much less than two minutes (usually a few ECG screens showing no electrical activity). The consensus of the SCCM ethics committee is that “no less than two minutes is acceptable, no more than five minutes is necessary given the IOM recommendation and the current practice of critical care medicine”.³

This conclusion raises some problems. First, it ignores many reports that demonstrate spontaneous restoration of adequate cardiac function after more than five minutes of asystole,^{19–24} a fact that is most probably grossly under reported rather than being remarkably rare.^{23 24} Even disregarding those papers, however, it must be noticed that Youngner’s data are seriously flawed from a clinical, methodological, and statistical point of view, so that they provide “the weakest possible evidence for a recommendation”.¹⁸ Because this recommendation concerns the weakest possible interpretation of irreversibility, the strength of the final conclusion can be questioned.

Second, the fact that one is bound to die without active intervention does not mean that one is dead. The paper recognises that circulation can be restored in many cases and that the brain will resume some functions, if resuscitation is successfully performed two to 10 minutes after asystole. Thus, it seems to mistake the “prognosis of death” for the “diagnosis of death”.

Third, even admitting the weakest possible interpretation of asystole, the irreversible cessation of all intracranial functions (brain death) cannot be considered certain at the time of organ harvesting. Thus, years after claiming that loss of brain functions is the only determinant of death,⁷ we have to certify death using cardiorespiratory criteria when the neurological ones are not yet met for certain. This option leads to an unstable and scientifically untenable situation in which death (with all its anthropological, social, and legal implications) is declared solely on the base of a moral position (the decision to forgo vital support) and a sequence of weak interpretations of the clinical data.

Fourth, the reference to non-potential organ donors is somehow misleading. Even if all patients are equal at irreversible asystole or a few minutes later, this event is not the time of death (which would render any subsequent approach to the patient irrelevant) but a somewhat arbitrarily defined “point of no return” in the process of dying. In this sense, while there is an evident social consensus for the forgoing of life support at this point, such a consensus is yet to be reached for organ retrieval.

Finally, the rationale behind NHBD programmes (with carefully designed protocols, it is possible to retrieve functioning vital organs after the donor’s “death”) might be acceptable for the kidneys. Yet, a major inconsistency dramatically emerges in declaring a patient dead on cardiovascular criteria and then proceeding to successfully transplant the heart.¹⁴

The problems outlined above are the consequence of the fact that medicine alone cannot diagnose death in such a short time: “waiting five minutes—or two or 10 minutes—after the cessation of cardiopulmonary function prior to declaring death is problematic . . . [as] the clinical data do not demonstrate when the criteria for death have been met”.¹⁸

The paper of the SCCM ethics committee moves apparently within the borders of the dead donor rule. Yet, if all these problems are left unsolved, one could fear that we are just playing with definitions and adapting them to what seems reasonable but not provable.

These questions cannot have escaped the members of the SCCM ethics committee, who are excellent clinicians and bioethicists. Most likely, they are well aware of all the issues and of the difficulty of proposing an alternative solution. This *cul de sac* is the consequence of the fact that the transplantation policy is based on the assumption that medicine can assuredly certify the biological death of the donors at a time when retrieval of viable vital organs is possible. This assumption is flawed.

ORGAN RETRIEVAL AND THE IMPOSSIBILITY OF DEFINING THE VITAL STATUS OF NHBD

As argued, we have no scientific means of diagnosing the biological death of NHBD.

We are reasonably sure that asystole is spontaneously irreversible after a few minutes. But whether at these moments those patients are really dead is a matter beyond our scientific knowledge and for which medicine has no answer.

The risk is that of creating socially acceptable criteria for transplantation by using “science” and “medicine” to legalise them, justify them, remove fear of abuse, and create widespread acceptance.

Some authors seem to suggest that, in fact, this is what happened with the brain death criteria.^{4 25–34} This hypothesis is indirectly confirmed by R Cranford, former chairman of the ethics subcommittee of the American Academy of Neurology, who, writing about persistent vegetative state (PVS), stated that:

It seems that permanently unconscious patients have characteristics of both the living and the dead. It would be tempting to call them dead and then retrospectively apply the principles of death, as society has done with brain death.³⁵

Even Henry Beecher, chairman of the Harvard committee, mixed up scientific, moral, and operational criteria, when he stated (in 1971):

At whatever level we choose to call death, it is an arbitrary decision. Death of the heart? The hair still grows. Death of the brain? The heart may still beat. The need is to choose an irreversible state where the brain no longer functions. It is best to choose a level where, although the brain is dead, usefulness of other organs is still present. This we have tried to make clear in what we have called the new definition of death.³⁶

The discussion of this problem is far beyond the scope of this paper and the disposable space. Nor do we think it is in anybody’s interest to call into question the righteousness of the concept of brain death 35 years after the Harvard criteria. Anyway, the mere fact that such issues exist forces us to be beyond reproach in our reasoning, keeping the different levels of discussion clearly separate, avoiding the mixing of what is scientific, what is moral, and what is operational.

A relevant factor is that the cardiorespiratory definition and criteria of death come from centuries of human experience,

when the cardiorespiratory functions were neither restorable nor supportable. Furthermore, for the first time in history we have the possibility of interfering in the process of dying with manoeuvres which are of no utility for the patient but which can greatly help others. In this sense, those criteria could be inadequate nowadays.

On the other hand, if death cannot be defined or identified by medicine alone, then medical knowledge and clinical states could become the tools for moral and social decision making. We suggest that we should move away from an unattainable certification of biological death, as the *sine qua non* for organ donation; we should openly admit that NHBD death cannot be defined at a time when organ retrieval is possible and that all we are able to define are socially, morally, and scientifically acceptable criteria for organ donation. Such criteria should be the object of wide debate (social, scientific, moral, ethical, and legal). They should also be the subject of constant review, as scientific progress and changes in moral paradigms are likely to require timely modifications. The only possible alternatives are either to abandon NHBD protocols or to maintain a scientifically untenable approach, pretending that NHBD are biologically dead.

In other words, if we want to continue to support organ transplantation from NHBD it's necessary to acknowledge the purely and typically moral and anthropological nature of the concept of death.

The challenge is to admit that medicine can only identify clinical situations (such as irreversible asystole) and stimulate a social discussion to establish if it is socially acceptable to retrieve vital organs from consenting patients in such a condition.

The real problem, consequently, can be formulated as follows: can we retrieve vital organs from patients if we cannot scientifically demonstrate their vital status, and in this way save other patients' lives?

The mention of transplant medicine is not inappropriate, even if it might seem better to avoid introducing the interests of a third party in such a discussion. Anyway, the fact that demand for viable organs was a major motivation for the implementation of NHBD protocols is well attested.^{11 37 38} Thus it might be better not to hide this issue but to clearly include it in the discussion of the problem.

The two relevant factors, therefore, are the interests and dignity of the donors and the vital needs of the recipients. Unfortunately, people in desperate need of vital organ exist. But thankfully there are also people who wish to donate their organs when they are no longer useful to themselves. Matching these two groups in a morally, anthropologically, and socially acceptable way can be an extraordinarily important goal.

SETTING A CLINICALLY DEFINABLE POINT OF NO RETURN

The approach we propose is to socially define irreversible (however defined) asystole as a point of no return in the process of dying of NHBD, where organ retrieval can be clinically, ethically, and socially justified.

After asystole, a patient's situation is quite out of our traditional concept of life and death. As minutes pass, more and more cells die, but still the moment of death is unknown. Most probably, such a moment is simply impossible to determine as an absolute value, because different patients "die" at different times after cardiac arrest. Declaring death in a moment which is consistent with the retrieval of vital organs is much more a moral than a clinical decision.^{18 26} Nevertheless, prolonged asystole is a clinically and scientifically useful point of no return, which can be used to guide moral and social decisions. As the irreversible asystole is the terminal event which precedes the biological death, the status

of NHBD could be defined a *post terminal condition*, as it follows the irreversible asystole (but clearly it's not yet biological death).

The approach outlined above is not absolutely original. Other authors have claimed the inadequacy of the current approach to the definition of NHBD vital status, together with the necessity of reformulating it on more scientifically tenable and morally acceptable criteria.^{26-28 39}

Shewmon, tracing an adequate moral background for the NHBD protocol, clearly admits that the patient is not yet dead at the moment of organ retrieval:

It is possible to remove vital organs from a patient just disconnected from extraordinary means of support but not yet dead, in such a way that death is neither caused nor even hastened. That is, organs are not touched until after final, though not yet irreversible, cessation of heart-beat and circulation; the heart is still resuscitable, but resuscitation prior to its excision for transplantation would constitute an extraordinary means appropriately forgone along with the ventilator. Excision of what would otherwise be a permanently non-beating heart in no way alters the circulation-less body's physiology during the remaining few minutes of the dying process. Informed consent is of course assumed.²⁸

Other authors^{26 27} are much more radical, deeming it reasonable and feasible to remove organs for transplantation (with the permission of the patient or surrogate) when the patient is either permanently unconscious or when death is imminent. Arnold and Youngner, for instance, wrote:

What if, instead of continually gerrymandering the line between life and death, we simply ask, "Are there some patients whose quality of life is so unacceptable and whose death is so imminent (by fate or their own decision) that we may take their organs before they die?" . . . After all, our society does not require that a patient be dead prior to the removal of life sustaining technology; it requires only that the removal does not violate the patient's interest (as defined by either the patient or surrogate). From a patient's perspective, the consequences of organ procurement (death) may not be that different than those of forgoing life support, except that organ procurement may help others.²⁷

The difference is that they all move within the strict dichotomy alive/dead, assuming that if a patient is not completely dead, he/she is still alive. Their position can be seen as an implicit violation of the dead donor rule and equated to euthanasia or active killing. Our position is that the traditional concepts of life and death are simply inadequate in the settings in which we have to make decisions, in the face of the continuing progress of resuscitation techniques, and the social needs represented by modern transplant medicine.

In addition to our observations, the theory formulated by L Emanuel is very interesting and somewhat similar. Assuming that in the process of dying there is no describable threshold event or state that clearly separates life and death, this author produced an asymptotic model which admits the reality of residual states of life and in which a bounded zone of life cessation can be defined. The persistent vegetative state (upper limit) and the irreversible asystole (lower limit) could bound such a zone. Death could be declared any time within the bounded zone, according to the patient's informed position:

A person's life must be considered ceased for any individual whose cardiorespiratory function has irreversibly

ceased, and can be considered ceased for any individual having neurological function no more than in persistent vegetative state if he or she or his or her proxy clearly indicate the wish that life be considered ceased in such a state.³⁹

Even this stance admits the current impossibility of medicine to determine reliable clinical signs of instantaneous death, but anticipates a sort of patient based, self tailored definition of death (with all its social, moral, and legal implications).

CONCLUSIONS

We have argued that it is not possible to define exactly at which point death occurs for the purpose of transplantation, because there are no scientifically tenable criteria to do this at the time when organ retrieval is possible. We believe that it is in the best long term interests of donors, recipients, their families, society at large, and transplantation medicine to be honest to ourselves, our patients, and society and admit that the only thing we can do is to openly formulate moral, social, and scientific criteria for organ retrieval.

As other authors have suggested in different ways, such formulation might involve a full reassessment of the organ donation process and of the definition of what society should accept for the process to occur. Our proposal is that, for the time being, it should rest on the currently applied criterion of irreversible (however defined) asystole, with the open admission that it does not define "death" but only a moment in the process of dying where organ retrieval can be allowed.

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