

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Give and take? Human bodies in medicine and research between April 2010 and July 2010. The views expressed are solely those of the respondent(s) and not those of the Council.

David W.Evans

Dear Ms. Wright,

Nuffield Consultation on Ethics of Human Bodies in Medicine & Research

I am pleased to hear of this open enquiry into the ethics of current organ transplantation (and other) practices and thank you for the invitation to offer my views to the Working Party.

Introduction

I have been concerned about these matters since being asked, some 35 years ago, to participate in the initiation of cardiac transplantation at Papworth Hospital - where I was, at that time, the only Consultant Cardiologist with the requisite expertise. When, after lengthy research and consideration, I came to the understanding that obtaining a viable heart for transplantation into a recipient necessitated its removal from someone who was not really dead but only notionally dead - death being redefined for the purpose - I declined to be involved. My decision delayed the start of that activity until the appointment of a cardiologist willing to assist the surgeons some four years later.

My first published protest appeared in *The Lancet* for April 26th 1980¹. The sentence with which Claude Lum and I ended that letter describes the diagnosis of death for the transplantation purpose - on purely clinical criteria designed and propagated as **prognostic** guidelines - as "a legal fiction" (adding "based on necessarily fallible medical opinion"). It is interesting to see that description applied to the misdiagnosis of death for transplant purposes today².

My consistent opposition to the transplantation of hearts - and of other organs procured from so-called "brain stem dead" donors with naturally beating hearts - led to such difficulties with my hitherto excellent colleagues, and latterly with my employers (who forbade open expression of my concerns), that I had to retire early in order to go on saying what I believed should be said. Much of my time and effort subsequently has been spent in trying to inform the professions and public about what has to happen if organs which will work in their new owners for many years are to be obtained from - usually inadequately informed, or even misinformed - donors.

Although some of my writings, alone or with others, have been published, I have signally failed to get the mainstream UK medical journals to inform their readers

even that there is, and has long been, active controversy worldwide about the diagnosis of death for transplant purposes. Sadly, they continue to turn a blind eye to the mass of literature expressing dissent from these utilitarian redefinitions of death – some of them officially approved – including, during the last few years, novel redefinitions based on very short periods of cardiac arrest. I mention the latter developments only to dismiss them as all too obviously contrivances for the provision of new sources of organs. I have personally restored effective cardiac contraction in literally dozens of cases of cardiac arrest of much longer duration, sometimes with the happy result of long and healthy survival of the patient subsequently. It should be abundantly clear that cardiac (and therefore circulatory) arrest observed over periods of only a few, or exceptionally even many, minutes cannot be considered permanent. Its irreversibility and the consequent inevitability of total brain necrosis - essential features of the state long known as death – cannot be assumed (at least without trial of defibrillation and other resuscitation measures, which are, of course, not used in this context) before very much longer periods of arrest, with concomitant body cooling etc., have been observed.

I have been equally unsuccessful in my efforts to get Secretaries of State for Health, MPs, Department of Health officials from CMOs down, Presidents (and the Academy) of Medical Royal Colleges, lawyers and journalists (with one or two exceptions), Archbishops, Bishops and the clergy generally – et al. – to take an active interest in what amounts to the misinformation of young doctors and the public, on a truly grand scale, in the interest of the apparently unchallengeable transplant industry. The long term consequence of this continuing deception may, I fear, be loss of confidence in the medical profession – with all that that entails.

I will append a short bibliography in the hope of assisting the Working Group's enquiry, noting that the anthology titled *Beyond brain death – the case against brain based criteria for human death*, edited by Potts, Byrne and Nilges³, which was first published by Kluwer Academic Publishers in 2000, is essential reading for all those with a serious interest in the attempt to redefine death on neurological grounds. Sadly, it is still not widely known here in the UK – perhaps at least partly because I was unable to get either *The Lancet* or the *British Medical Journal* to review it or otherwise bring it to the notice of their readers.

My specific response

Having offered some explanation of my active involvement with these issues over the years, I now propose to set aside my wider interest in the science and ethics of organ transplantation – and in the several other elements of your Working Group's brief – and offer a response to the question your *Consultation Paper* asks "**What constitutes valid consent?**". In answer, I will order and number my comments in the hope of aiding clarity and possible discussion.

1. Telling the truth

I assert the primacy of the full and frank description of all aspects of organ transplantation practice in any sincere examination thereof. I assume the Working Party's agreement that this is paramount and, this being so, that it will demand the fair information of all those involved in the activity. This will require the formal recognition that a generation of doctors has been erroneously taught that "brain stem death" is death – a concept without sound scientific or philosophical basis (*vide infra*) – and the admission that millions of people have been persuaded to enter their names on the NHS Organ Donor Register on a false premiss, viz. that they have been assured that they will be dead before their organs are removed.

2. The redefinition of death for transplant purposes

In a matter of such fundamental importance as the death of a person it may seem remarkable that so many new concepts and redefinitions of death have been invented, and given credence, for the purpose of providing transplantable organs – an enterprise which proved sensationally captivating and was soon seen as an unequivocally "good thing", apparently exempt from ethical and rational challenge – although that enterprise could never contribute materially to the relief of human suffering on even the national scale. The reason for these reinventions of death – all of them anticipating the arrival of the dying person in that final state universally recognised as death – is what has become known as "the dead donor rule". That is to say that it was – and probably still is – considered unacceptable to take vital organs from the still living. Hence the necessity to diagnose death on some new basis while the body containing the wanted organs is still alive (for one cannot obtain viable organs, capable of long term function in another body, from a cadaver).

There was no agreed basis for the diagnosis of death on neurological grounds when Barnard carried out his first heart transplants in Cape Town in 1967 but the following year an ad hoc committee at Harvard published a procedure for the diagnosis of irreversible coma⁴ which it identified with death of the brain and this became the basis for the certification of death of organ donors while their hearts were still beating and perfusing the wanted organs. This practice, which gained Federal statutory status after the US President's Commission Report⁵ in 1981, and was subsequently adopted in all the United States, was based on the concept of "whole brain death" – the death (final cessation of function in all parts) of the whole of the brain. The certification of death on a diagnosis of brain stem death alone has never been accepted in the USA, although that diagnosis is, of course, a necessary part of the whole.

In the UK, purely bedside tests for the diagnosis of the premortal clinical syndrome which became known as “brain stem death” were published in 1976 - as guidelines for the management of ventilator-dependent patients with no hope of recovery⁶. Those same tests, for absence of medullary respiratory centre response to elevated carbon dioxide tension in the arterial blood and to tests for the integrity of some reflexes with pathways through the brain stem, were subsequently held (in 1979)⁷ to suffice for the diagnosis of death of the brain and therefore of the person. No rational argument for this change of use from prognostic to diagnostic (of death) was advanced then or since. Nor was there offer of scientific support for the claim that these few simple tests of some brain stem functions had the power to diagnose death of the brain – in which much activity was still readily demonstrable but not sought. That manifestly untenable claim was finally abandoned by the Conference of Medical Royal Colleges⁸ in 1995.

For a full account of this sad story of false claims by such an expert and authoritative body, in an age of supposedly science-based Medicine, I must ask members of the Working Group to read my chapter titled ‘The demise of “brain death” in Britain’ in *Beyond brain death – the case against brain related criteria for human death*⁹. The motivation for those claims became clear when cardiac transplantation started in their wake at Papworth in 1979, despite the existence of a Departmental moratorium on such procedures after the disastrous attempts some 10 years earlier.

3. Current UK practice

Since 1995 there has been no pretence that the UK Code of Practice for the diagnosis of death on neurological grounds has the power to diagnose death of the whole brain. But it is still claimed that it suffices for the diagnosis and certification of death – particularly so that organs can be removed from a patient so certified without inviting legal challenge. The basis for this continuing use of essentially the same diagnostic criteria for this purpose is now the quite different claim that, when the tested brain stem reflexes are absent and there is no response to the specified increase in arterial carbon dioxide tension, there can never again be any possibility of the return of consciousness or of spontaneous breathing. That claim – at first sight little short of breathtaking, given the very simple nature of the purely bedside tests upon which it is based – proves, on close examination, to be without sound scientific support. Neither can that concept of human death be held to enjoy universal, or even widespread, philosophical support – as submissions to the Working Group from those with expertise in that discipline may make clear.

The largely hidden assumption underlying *the first element of the 1995 concept* and claim⁸ is that the generation of consciousness is fully and certainly

understood. That is, in the present state of knowledge of the brain's functions and plasticity, very far from the case (and it may never be understood¹⁰). The current Code of Practice claim that, when its tests of some brain functions are negative and complete, there can never again be any "capacity for consciousness" depends upon an old and imperfect theory of consciousness¹¹ which requires persisting function in elements within the brain stem – but also present elsewhere in the brain – to "arouse" the higher centres (such as the cerebral cortex). There is, in any case, no means of testing that arousal system. It can be said to be permanently out of action only by implication, i.e. if it can be shown that the whole of the brain stem (and, perhaps, other parts of the brain) are destroyed. The tests prescribed in the Code of Practice – for the diagnosis of so-called "brain stem death" – lack the power to establish that state as a matter of fact¹². From the outset there was concern that the persistence of blood pressure control signalled continuing life within the brain stem and there have been many subsequent technical studies (e.g. of evoked responses and oesophageal mobility) documenting life therein.

The second element of the Code of Practice concept of death is equally unsatisfied by the test prescribed. The medullary respiratory centre is never challenged by the ultimate drive stimulus – anoxia. In fact, when the test – the apnoea test – is done prior to use of the patient as an organ donor, great care is taken to ensure (by prior oxygenation and diffusion oxygenation during the test) to prevent anoxaemia which might be harmful to the wanted organs. But if the patient is not to be used as a donor and mechanical ventilation is permanently withdrawn after diagnosis of "brain stem death" on the Code's criteria, it is not unknown for agonal gasping to occur when the centre is eventually subjected to the anoxic drive stimulus at the time of final cardiac arrest. Rarely, there may also be purposive movements suggesting hitherto unsuspected integrative brain function.

[Mention of apnoea testing requires reference to its risks which include exacerbation of the brain damage and causing the death for which it is testing^{13,14}].

In light of the above it will be understood that ***there is no sound scientific basis for diagnosing death on the current Code of Practice criteria***. Nevertheless it is said that death certification on that basis is accepted in English law. If that is indeed the case, perhaps it has something to do with the fact that Her Majesty's Judges have never heard the scientific arguments presented without bias. Had they been asked to consider the evidence on its own merits and in isolation from emotive issues such as organ transplantation, it is difficult to conceive of their failing to recognize the specious nature of the pseudoscientific arguments so successfully used by protagonists of the "brain stem death *is* death" fallacy.

4. Worldwide review of redefinitions of death for transplant purposes

There has been such active criticism of the various “brain death” and other redefinitions worldwide, particularly in the USA, that the US President’s Council on Bioethics made a formal enquiry into the controversy and produced a White Paper titled *Controversies in the Determination of Death*¹³ in 2008. That publication, and especially the Personal Statement of its Chairman¹⁴, is required reading for members of your Working Group. In the context of this specific response, I direct attention to page 66 of the White Paper where the Council distances itself from “the UK neurological standard”. It describes “death of the brainstem” alone, rather than total brain failure, as an insufficient criterion for declaring a patient dead. Such a reduction, it asserts, is both “conceptually suspect” and “clinically dangerous”. [In the interest of scientific truth and sound medical practice, it must be said that neither state - death of the brain stem nor death of the whole of the brain - is reliably diagnosable as a matter of fact, at least before the final cessation of blood flow through all parts of the brain, by the techniques available in clinical practice today].

5. Proposed abandonment of the “dead donor rule”

Such is the increasing realization that organ donors are not dead when so certified and operated upon that, perhaps because it is thought that the false claims that they are dead cannot be maintained for much longer, there have now been many calls for abandonment of the requirement that death precedes evisceration. It is argued that no harm is done, and no ethical boundary crossed, if consenting (or even conscripted) dying patients are dispatched, kindly and with appropriate relief of suffering, by their doctors in the course of removal of their organs, in prime condition, for the use of others. It is interesting that some of these calls originate from Harvard, where the stage was set for the explosion of organ transplantation by the machinations of its ad hoc committee in 1968.

Robert Truog has been one of the chief protagonists in this development, his open-ness and honest descriptions of the true state of organ donors being most welcome in this world of obfuscation for utilitarian ends. His 2003 paper with Robinson¹⁵ states clearly that “the concept (*of brain death*) fails to correspond to any coherent biological or philosophical understanding of death”. While readily agreeing on that point, we could not, and cannot, accept the proposal that patients should be killed for their organs¹⁶. Ever more strident appeals for this change continue to appear, now extended to the mooting of euthanasia for the specific purpose¹⁷. However, some comfort may be sought in the observation that even those most enthusiastic for change, while regarding it as a “moral fiction that donors are dead when vital organs are procured”, regard abandonment of the “dead donor rule” as unlikely in the near future¹⁸.

6. The status of organ donors when their organs are removed under the rules operating in the UK today

It will be clear, from the foregoing, that they are not dead in any ordinary understanding of the term although certified dead before surgery begins. The grounds for that certification are, to say the least, contentious. It is a fact, though not sufficiently known and appreciated, that there is no consensus about the diagnosis of death on any of the – more than thirty – versions of “brain death” in use for organ procurement purposes worldwide. The reductionist UK version of “brain death” – so-called “brain stem death” – is specifically rejected by the US President’s Bioethics Council and by many countries in Europe and elsewhere, although still used (not without criticism) for organ procurement purposes in Commonwealth countries.

Donors certified dead under current UK Code of Practice rules may retain brain functions such as blood pressure and heart rate control, body temperature and urinary salt secretion (and other hormonal) regulation, and the ability to nurture a foetus to term, as well as reflex responses which may involve cerebral modulation. It is not known whether or not they might retain function in visual and olfactory pathways (which are not tested). Their persisting muscular reactivity is controlled by paralyzing drugs in the interest of surgical facilitation. Even so, they show cardio-accelerator and pressor responses to the surgical trauma which may be brain stem mediated.

It may be that many or even most people in this country would not, if they knew and fully understood all the relevant facts, regard that state (of organ donors as the organ procurement surgery begins) as death. Many relatives, seeing them in that state when identified as potential donors, recognize that they are still alive and refuse consent to such use. My personal experience of questioning carriers of Organ Donor Cards is that almost all of them have seriously incomplete understanding of the state they will be in if their offer is ever taken up, most of them cherishing the thought that their brains will be dead.

7. The issue of consent by prospective donors

Unlike consent to surgical procedures for (even minor) therapeutic purposes which, to prove valid in case of legal challenge, have to be fully informed and witnessed, consent to the use of a person’s body as a source of organs is considered to have been obtained when he or she registers on the NHS Organ Donor Register. This may be done by ticking a box on part of a Driving Licence application form, or some similar form standing in isolation or attached to some other document, e.g. a store card. Or, these days, registration may be effected by ticking a box on-line. In all these cases, the wording of the offer so recorded

is the same. It says, clearly and unequivocally, that the specified organs offered will be taken "*after my death*".

There is no explanation of the highly relevant fact that, if the registered person is used as an organ donor, his or her death will be diagnosed on a different basis from that in ordinary, everyday, use. Accompanying literature may contain (usually partial) explanations that death for transplantation purposes is a special case requiring specialist doctors, using their special expertise (but only simple bedside tests) for its certification – the vast majority of doctors, however experienced, being deemed incompetent to diagnose death on these special grounds – but no evidence is required of the registrant's understanding of this very important different use of the common term. That same explanatory literature may also contain unwarranted assurances based on specious arguments, bad science and controversial concepts and criteria – as we have seen above.

[The current registration document, which I picked up at my GP's surgery today, contains no explanatory information whatsoever].

The long and short of this contentious matter is that "consent" obtained in this manner cannot be considered valid. The two parties to the offer may well not be, indeed probably are not, *ad idem* in regard to its terms. In particular, those taking up the offer will have an understanding of the word "death" which is unlikely to be shared, or even fully comprehended, by the person making it.

8. The issue of consent by next-of-kin

While this may differ according to whether or not the wishes of the ventilator-dependent patient were made known during his conscious life, I propose to deal with it as a single case because it is possible, or likely, that any expressed wish to donate organs after death was not fully informed and was therefore invalid. Indeed, I have long thought that the high rate of refusal by parents to offer sons' and daughters' organs has much to do with their perception that their children are not really dead when pronounced "dead" for transplantation purposes and their concern that, if they had made offers of their organs, they cannot have understood the state they would be in if such offers were ever taken up.

Requests for permission to use the organs of identified potential donors are usually made by specially trained transplant coordinators.[In current practice, this applies to those potential donors who carry Donor Cards, as well as to those not registered on the NHS ODR, although this may no longer be legally necessary].These transplant coordinators are adept at empathizing with those soon to be bereaved and skilled at answering their questions in the officially approved fashion. Lacking the specialized knowledge of neurophysiology which engenders proper doubt, they may be more successful than doctors in

convincing relatives that their next-of-kin are, at least in some sense, dead – and sincerely unaware that their assurances to that effect are not based on sound science. That said, the question of full and frank information of the relatives, and their clear understanding of the true state of a person pronounced “brain stem dead” – bearing in mind the distraught state of minds trying to comprehend and come to terms with loss – must be seen as wide open. The “consent” thus obtained must be considered of very doubtful validity.

On a *personal note*, I have to say that – knowing, as I did, the true state of “brain stem dead” organ donors and what has to happen for their organs to be procured in a condition suitable for transplantation - I could never have given permission for one of my children to be so used. To me, that would have entailed the betrayal of that absolute trust that a child properly has in his or her parents. How could any loving father allow his son to be dispatched while still so much alive – while there was still so much persisting (but undemonstrated and unsought) brain function, including the **possibility** of remaining consciousness in some form (for we do not know where or what consciousness is, or how it is generated from whatever may be the minimum necessary neural substrate)? Even the remotest possibility of his suffering, paralysed but perhaps not even lightly anaesthetized, during his evisceration for the sake of some third party, would be sufficient to decide the issue for me.

I have pondered why so many parents have allowed their children to be so appallingly misused and have been forced to the conclusion that it can only be because, unlike me, they did not really understand the relevant facts when they gave their consent.

9. What needs to be done?

- a) There must be full and frank information of the professions and public about these (and other) aspects of transplantation practice, on a scale comparable to the massive propaganda used to form public attitudes to these procedures during the past thirty years. Only then will it be possible to know to what extent they enjoy public and professional support.
- b) All those on the NHS ODR should be contacted, given the facts in assimilable form, and asked if they wish to remain thereon.
- c) Requests for organs from identified donors should be made only by doctors with authority to answer questions honestly and factually – being prepared to admit lack of knowledge where appropriate – and without hint of persuasion by suggestion of over-riding third-party interests or otherwise.

- d) The long term requirement is for abandonment of spurious attempts to redefine death for transplant purposes and reappraisal of organ transplantation generally. The latter exercise will necessitate careful consideration of the growing practice of organ procurement from healthy living donors. This practice offends against the fundamental principle of good medical practice – *primum, non nocere*¹⁹. Doctors cannot be involved in such activities without risk to that trust which the medical profession has long enjoyed and which is so essential to the doctor-patient relationship.

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11. The claim that the specified bedside tests have the power to diagnose irreversible loss of the capacity for consciousness depends upon the assumption that they have the power to determine the permanent loss of the intrinsically untestable consciousness-arousal function of those elements of the reticular formation which lie within the brain stem (there are elements also within the higher brain). Knowledge of this arousal system is based upon the findings from animal experiments as illuminated by pathological studies in man. The current neurological consensus is that the arousal of consciousness depends upon reticular components which reside in the midbrain, diencephalon and pons (Bleck TP in *Textbook of Clinical Neurology*, 3rd Edn, Ed. Goetz CG, Elsevier Science, 2007) . It is said that the midbrain reticular formation may be viewed as a driving centre for the higher structures, loss of which produces a state in which the cortex appears (on the basis of electroencephalographic studies) to be awaiting the command or ability to function. The rôle of diencephalic (higher brain) involvement is stated to be uncertain and we are reminded that the arousal system is best regarded as a physiological rather than a precise anatomical entity. There should, perhaps, also be a caveat about possible arousal mechanisms involving the first and second cranial nerves (serving sight and smell) which are not tested when diagnosing 'brain stem death' but which were described in cats in 1935 and 1938. There is also concern about the permanence of consciousness loss, based on studies in cats, dogs and monkeys which recovered consciousness days or weeks after being rendered comatose by brain stem ablation and on human studies of brain stem stroke raising thoughts about the "plasticity" of the nervous system. Other theories of consciousness place more stress on the thalamocortical system. Perhaps the most objective statement to be made is that consciousness is not currently understood. That being so, proper caution must be exercised in accepting a diagnosis of its permanent loss before all cerebral blood flow has permanently ceased. [References available on request – DWE]

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Conclusion

I trust the above observations, opinions and sources of relevant information will be of assistance to the Working Group and look forward to hearing its conclusions. Should there be interim statements in which you think I may be interested, I will be most grateful if you will make them known to me. Needless to say, I will be more than happy to amplify aspects of the above, and to discuss points which may arise from them, should the Working Group so wish.

Yours sincerely,

David W.Evans