Non-heart beating organ donation: old procurement strategy—new ethical problems

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The imbalance between supply of organs for transplantation and demand for them is widening. Although the current international drive to re-establish procurement via non-heart beating organ donation/donor (NHBOD) is founded therefore on necessity, the process may constitute a desirable outcome for patient and family when progression to brain stem death (BSD) does not occur and conventional organ retrieval from the beating heart donor is thereby prevented. The literature accounts of this practice, however, raise concerns that risk jeopardising professional and public confidence in the broader transplant programme. This article focuses on these clinical, ethical, and legal issues in the context of other approaches aimed at increasing donor numbers. The feasibility of introducing such an initiative will hinge on the ability to reassure patients, families, attendant staff, professional bodies, the wider public, law enforcement agencies, and the media that practitioners are working within explicit guidelines which are both ethically and legally defensible.

Figure 1 Current donor organ sources.

APPRAISAL OF THE POTENTIAL ORGAN DONOR POOL AND THE INHERENT ETHICAL ISSUES

The greatest current source of transplantable organs in the Western world is the hospital based cadaveric donor (see figure 1). Other countries have alternative organ sources15 or in the face of non-acceptance of the concept of brain stem death,16 rely on the living to donate. Living related donation, given the shortage of cadaveric organs, is a significant aspect of practice worldwide, and although traditionally limited to a solitary kidney, has now extended to removal of liver or lung lobes, procedures not without hazard.17 It raises concerns as to validity of consent, in turn based on accurate information not only on immediate and longer term donor mortality and morbidity, but on graft function within the recipient,18 certainly an issue with the older donor.19 The other ethical issues regarding the inevitable explicit or implicit coercion inherent in living donation have been debated.20 The altruistic act of anonymous living donation has also been described,21 but although there is evidence that up to 32% of the population in British Columbia would be prepared to donate a kidney whilst alive to a stranger,22 it is difficult to expect that this will make major inroads into the deficit, and the process inevitably comes with an ethical dimension.23 Commercial traffic in organs is illegal and to this end any unrelated living donation in the UK requires the prior approval of the Unrelated Live Transplant Regulatory Authority (ULTRA).


**OPTIONS FOR INCREASING THE CADAVERIC DONOR POOL**

The above problems associated with living donation lead to scrutiny of either the process of dying, or of recruitment of the brain death population, to increase the donor pool (see table 1). Suggestions that the definition of death be expanded to allow procurement from anencephalic infants and patients in the permanent vegetative state (PVS) involve a degree of sophistry unable to be accommodated under current laws and even if this were to change it is difficult to expect that there will be widespread public tolerance. It is indeed possible that such attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are cumulatively jeopardising public confidence in the current programme in the manner of airing of previous attempts are 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Categories of patients that raise serious questions.

A fundamental concern revolves around definitions of death and this needs to be placed in the context of debate over the last 40 years. The recognition that medical advances could sustain cardiac activity whilst progression of intracranial pathology resulted in whole brain death, generated a need to evaluate concepts of death. It can be argued that the definition of death to include this product of medical intervention was simply utilitarian, facilitating optimal organ procurement that could not be legitimately conducted on anything other than a cadaver. Aside from this vexed issue, however, the futility of ongoing supportive care is understood and accepted by a majority of the civilised world. The redefinition furthermore clearly established the need for death before organ retrieval.

A greater difficulty with definition has been created by cortical death after brain injury whereby spontaneous respiratory effort is retained in conjunction with cardiac activity, and long term survival is possible with nutritional support and general care. Whilst at the extreme end of the spectrum of PVS the patient will display a complete lack of sentence equivalent to the brain dead patient, leading to calls for a further redefinition of death and indeed utilisation for organ donation, the very fact that a spectrum of neurological deficit exists, negates the use of a term, death, which must be absolute to avoid discrediting the original expansion. Indeed, despite the immense dilemmas created by end of life decision making in this cohort of patients, no professional body or legislation has ever considered them other than alive.

Medical advances have also created problems in applying death as an absolute generic term in the context of traditional death. A clinical state compatible with classical death, characterised by unresponsiveness and absence of cardiac output and respiratory effort may within a short period of time reverse spontaneously (auto resuscitation) if due to a disturbance of cardiac rhythm, and may be reversed by interventional resuscitation over a slightly longer time frame with no neurological deficit. This clinical state cannot therefore be directly equated with classical death, regardless of the likelihood or inevitability over time of classical death without intervention. The patient could more accurately be described as dying rather than dead.

Resuscitation beyond a three to five minute watershed after classical death can also restore cardiac output and respiratory effort. Although, in the absence of protective factors, the patient will invariably demonstrate an extreme neurological deficit, they will, however, be defined as alive.

These factors are acknowledged within virtually all American states under the Uniform Determination of Death Act whereby death is defined by cardiovascular criteria only once it is irreversible. Although the main driver for the legislation appeared to be the protection of physicians using brain orientated criteria, the cardiovascular criteria appear unequivocal and it is against this template that the approach as regards NHBD can be judged.

The Maastricht workshop considered that 10 minutes without perfusion of the brain was necessary before any intervention geared towards organ retrieval, and the Institute of Medicine recommended a five minute observation period. The Pittsburgh protocol sanctions surgical retrieval of organs at two minutes after asystole, which appears incompatible with the above statutory cardiovascular definition of death, whereby the loss of functions used to determine death should be irreversible. Furthermore, the possibility of sentience at retrieval, although remote, appears intuitively higher than for a case of established brain stem death and it must be accepted that medical practitioners have raised questions as to the latter possibility. Evidence to suggest that neurological functions considered irreversibly lost may be restored is likely to fuel such speculation, leading to public uncertainty and the possibility as previously described, of derailing the transplant programme in general (Panorama, Transplants: are donors really dead?, BBC2, 13 Oct 1980). Furthermore, the expansion of this procurement practice, with many units not having any or any approved policy would also serve to generate disquiet.

Practitioners at Pittsburgh have sought to answer criticism that irreversible loss of brain function would not have occurred at two minutes, with the arguments that irreversible lack of cardiorespiratory function is sufficient to certify death and that since the patient or family have refused resuscitation, the clinical state is clearly irreversible. It would be easy to dismiss this as professional sophistry were it not for the fact that outside the setting of organ donation, death is routinely, legitimately, and legally certified within the timescale of two minutes, in scenarios when death is expected, including after withdrawal of supportive care. Indeed, it would be considered unreasonable if families had to wait at least 10 minutes after asystole, apnoea, and unresponsiveness before the patient could be considered dead. It would appear somewhat illogical therefore if different criteria for cardiovascular death were applied dependent on whether organ retrieval was countenanced.

Although different definitions of irreversible and the different time scales described above are hardly conducive to public

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### Table 2 Strategies to improve the viability of organs from the non-heart-beating donor

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tr>
<td>1. The uncontrolled donor (category I &amp; II)</td>
<td>- provision of cardiopulmonary resuscitation after death&lt;br&gt; - cannulation of the femoral vessels and organ perfusion&lt;br&gt; - presumed consent to undertake the above in the absence of next of kin</td>
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<tr>
<td>2. The controlled donor (category III)</td>
<td>- trial of withdrawal of care&lt;br&gt; - administration of drugs; steroids, antibiotics, heparin and vasodilators&lt;br&gt; - cannulation of the femoral vessels to facilitate early organ perfusion&lt;br&gt; - early diagnosis of cardiovascular death&lt;br&gt; - rapid retrieval of organs after diagnosis of cardiovascular death</td>
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ment team is not ready or the family have not reached a ment is inappropriate or has been refused, when the procure-
of resuscitating those patients for whom life sustaining treat-
permissible, by complying with their wishes, use of these agents is claiming that since donation benefits the patient and family could fall within the definition of active euthanasia. To of life demonstrate at best conflict of interest and at worst could encompass within the conventional backstop of double effect. The impact of agents given solely to optimally preserve organ function also generates concern in this regard. It can be argued that use of heparin as an anticoagulant is of little systemic consequence, but the capacity to aggravate bleeding carries the accompanying capacity to cause a deterioration in cardiovascular performance. The use of phenolamine, a vasodilator, is certainly open to questioning since the inevitable fall in blood pressure clearly has the potential to expedite death, particularly in the established critically ill. Such recommendations that are available allow interpretation of the word “harm” and do not advise absolutely against these agents in stating: “medications that do not harm the patient and are required to improve the chances of successful donation are acceptable”. It would thus appear that elements of care towards the end of life demonstrate at best conflict of interest and at worst could fall within the definition of active euthanasia. To sumsoms the protection of the principle of “double effect” by claiming that since donation benefits the patient and family by complying with their wishes, use of these agents is permissible, is an extreme example of professional sophistry. Conflict of interest is also reflected in the converse practice of resuscitating those patients for whom life sustaining treat-
ment is inappropriate or has been refused, when the procure-
ment team is not ready or the family have not reached a decision. Although this would fall within the category of assault if consent had not been obtained, it could be argued that if the patient had expressed a wish to become a donor, this practice could reasonably be accommodated as a means of achieving that goal.

The practice of cannulation of the patient prior to withdrawal of care for the purposes of preservative perfusion is also open to varied interpretation and it is of note that this practice is not prohibited by the recommendations above. It could be argued that interventions of this nature would require an escalation of analgesic and sedative or anaesthetic agents with the potential for destabilisation of the cardiovascular system, thereby precipitating, or priming for, a more rapid death. This process too could not comfortably be contained within the principle of “double effect”.

Although the American approach comes with the redeem-
ing feature of openness through publication, there are many areas of ethical disquiet, not least because of the diversity of process. It is difficult to determine whether other countries such as Holland and Japan adopt a uniform defensible template in their practice of controlled NHBOD and information from the UK is also extremely limited as to the extent and nature of practice.79

KEY PROBLEMS WITH PROCUREMENT STRATEGIES FROM CATEGORY 2 PATIENTS

The process of “uncontrolled” organ procurement as practised in Leicester, UK is, however, published. Patients admitted to the A&E (accident and emergency) unit with a history of cardiopulmonary arrest either outside or within the department were targeted. The entry criteria for inclusion in the procure-
ment process were, in the absence of disease, an age below 65 years, and a period of circulatory arrest without basic life support of less than 30 minutes. It is not specified by which criteria resuscitation manoeuvres were discontinued, but death was certified by cardiovascular criteria. Once certified, the patient was moved to the A&E operating theatre where ventilation and cardiac massage were carried out either manually or mechanically (Thumper CPR System—Michigan Instruments). In the absence of the family to approach for consent a surgical cut down of the femoral vessels in the groin was con-
ducted prior to insertion of a perfusion catheter into the aorta and the instillation of cold preservative solution. This process would be continued until the family could be contacted and asked for consent. This category of procurement raises similar questions regarding a valid definition of death as outlined above in relation to category 3 patients. It is uncertain whether the law would consider the patient alive or dead but certain parallels can be drawn from the process of “elective ventilation”. It was stated in defence of that practice by the authors that the intervention of ventilation was initiated at the moment of death, with the actual diagnosis of death at some later stage by formal brain stem death testing. This flexible interpretation of death using different criteria was not considered sufficiently absolute and robust to contain the practice within the law and this viewpoint could equally be adopted with regard to procurement practice for the category 2 patient.

Concerns are generated not only regarding the validity of the diagnosis, but by the practice of cardiac massage and ven-
tilation with 100% oxygen after the diagnosis of death, prior to the establishment of renal perfusion. Depending on the period of asystole, it is not inconceivable that re-establishment of cerebral perfusion may be associated with some restoration of brain function. Dilated unreactive pupils in the context of card-
iac arrest may be attributable to the use of agents such as adrenaline and atropine, and even in the absence of these drugs, do not unequivocally predict a poor neurological outcome. This in turn raises questions as to a definition of death and the timing of such. If the patient is potentially alive, even though death is inevitable, the continuation of CPR (cardiopulmonary resuscitation), the surgical placement of aortic catheters and the administration of organ preservatives is clearly not in the patient’s best interests and constitutes an assault in a similar vein to “elective ventilation”. There is a paucity of statute covering this area but the common law position in England for the incompetent patient is that a doc-
tor may only initiate and maintain treatment that is considered by professional opinion to be in a patient’s “best interests” and by invoking the doctrine of “necessity”.81 82 Given that within England no person or body has the authority to offer consent on behalf of an incompetent adult for any
aspect of care, the stated consent of the family, coroner, and ethical committee described in the above publication would not carry legal validity. If the patient could legitimately be considered dead, these interventions would acquire a different connotation. The Human Tissue Act 1961 allows for persons lawfully in possession of a body to remove parts for therapeutic purposes either with the expressed wishes of the deceased and/or in the absence of objection of relatives. The process of procurement described above does not comply with these directives. The interventions as a prelude to organ retrieval are seemingly outwith the definition of "removal" and in most cases the process is initiated without authorisation by patient or family. It is unclear whether interference with a corpse without legitimate authority would be considered a crime at common law, there being no property in a body. The courts do recognise, however, that whoever is responsible for disposal of the body does have a possession right and interference with this right could clearly create liability. Although this process cannot be viewed in the same vein as indecent interference, which the law will not allow, it could also be construed as mutilation, which although purposeful, may be actionable. The possibility also exists of the deceased's relatives raising a claim for psychiatric injury, particularly if the interventions have been witnessed, a factor key to litigation success in previous cases. Even without these considerations it can be argued that although the general public may accept that a corpse cannot be harmed, respect for the dignity of the human body is likely to be widespread. The process could easily be interpreted as a lack of respect for the human body, the patient, and indeed any concerns that the family may hold, thereby engendering mistrust and antipathy towards the process of organ donation. Furthermore, the interventions prior to organ retrieval would appear to be based on "presumed consent" and it is possible to invoke the "slippery slope" argument that once this practice has become established and thereby accepted, progression to retrieval on this basis is not such a major clinical, ethical, or legal hurdle. Mistrust is a likely consequence of public awareness of this process.

CONCLUSIONS
It has been estimated that the number of donor organs could rise by 25% through the expanded use of NHBOD making it inevitable, in an era of universal shortage, that there will be pressure to procure from this cohort of patients. All transplant procurement strategies come with an ethical dimension but this particular process raises multiple concerns, not least of which is ambiguity as to the timing and definition of death. Given the disquiet with the concept of brain death it is difficult to see how the differences in interpretation described above can contribute to public and professional confidence. The need for rapid progression to cardiovascular death in the era of donor-organ shortage. Lancet 1999;354:1636-9. Burdick JF, Turcotte JG, Veatch RM, et al. General principles for allocating human organs and tissues. Transplant Proc 1992;24:2227.
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