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Editorial II

Non-heart beating organ donation: in urgent need of intensive care

Cadaveric organ transplantation has evolved over the last 50 yr from experimental undertaking to consistently successful treatment for irreversible disease. Progressive refinement of organ procurement and preservation, surgical technique, perioperative care, and immuno-suppression have all contributed to this success, which has inevitably fuelled demand. Limited donor organ availability is now the greatest barrier to successful transplantation, driving a range of recruitment strategies and creating new challenges. Non-heart beating organ donation (NHBOD), whereby retrieval follows cardio-respiratory death, represents a return to the original source of cadaveric organs, largely abandoned when the brainstem-death concept facilitated retrieval of vital organs at optimal viability. Unmet need and evidence of satisfactory function have, however, prompted piecemeal re-adoption of NHBOD over the last decade.

In this month's journal, Thomas and colleagues[1] describe the introduction of NHBOD within a UK neurosciences intensive care unit. Their summary position is that the process appears logistically feasible, generates donor numbers approximating to the brainstem-dead population, and provides kidneys of longer-term equivalent viability. Such observations rationally underpin the authors' advocacy for widespread adoption, routine consideration of donation whenever support is withdrawn, and transfer of care if clinicians harbour objections. With governmental promotion[2] and endorsement by the national professional body, the Intensive Care Society [ICS],[3] any observer may consider those recommendations reasonable and question any individual or unit not embracing this initiative. However, NHBOD has proved the most contentious topic within the UK intensive care community over the last 5 yr. Outspoken opposition[4] and little uptake demonstrate persistent clinician concerns as to ethical defensibility, lawfulness, and individual vulnerability. Readers may be disappointed therefore that the Bristol authors, despite referencing this opposition, do not explore how these hurdles were sustainably overcome within their institution. Such polarization of professional views and approach to patient care, at a time when society expects standardization, is an interesting phenomenon, but one overshadowed by the attitude and authority of both government and transplant fraternity in a more recent national recruitment strategy.[5] This implicitly targets an expansion of NHBOD, and although the ethico-legal hurdles are acknowledged as requiring resolution, the proposed measures, without that resolution, have the potential to further drive opposition by clinical staff who have reservations.

It appears relevant, therefore, to explore these complex interconnected issues; the process itself, the clinical and professional body response, and the approach of government through the Department of Health, to determine whether common ground may exist and whether solutions acceptable to all parties are feasible.

The alternatives to and drivers behind re-adoption of NHBOD are well described, and not specifically pertinent to the current debate.[6] The ethical and legal implications, defined for the intensive care community by 2003,[7] and debated at the annual meeting of the ICS in association with senior representation from UK Transplant and Office of the Official Solicitor, remain significantly unresolved, however, creating the spectrum of opinion described above.

Avoiding conflict of interest when defining ongoing support as futile, the lawfulness of investigations and interventions undertaken to achieve donation at optimal viability, working within an unambiguous universally acceptable definition of death, and ensuring valid standards of consent, all require explicit resolution if practitioners are to embrace this recruitment strategy.[8]

The Transplant Framework for England, *Saving Lives, Valuing Donors*,[2] in proposing NHBOD to increase transplantation rates, simply stated (para 5.9): 'There are recognised differences in international practice and procedures relating to non-heart beating organ and tissue donation. We will therefore work with relevant professional bodies to develop clear national guidance to support these programmes'.

In considering whether those intentions have been fulfilled within the above four fields of discord, it is relevant to review ICS undertakings in collaboration with Department of Health, UK Transplant and Office of the Official Solicitor, which were placed before the anaesthetic community in 2005.[3]

Conflict of interest during decision-making on futility is implicitly recognized, but considered satisfactorily

addressed by adherence to professional guidelines on the withdrawal of life-sustaining medical treatment.[9]

The need to explain the process of donation in detail to the patient's relatives is set out, although there is no specificity as to format, that is, written or verbal, whether the content should refer to the ethico-legal problems and range of opinion on these matters, and no indication as to who should be responsible.

The position on permissible interventions before withdrawal of support is a curious combination of conservatism and challenge to established guidelines and the law, which admittedly was in a state of flux at that time. The position before implementation of the Human Tissue Act 2004 was defined by the 1983 Code of Practice for transplantation which stated: 'any tests or treatment carried out on a patient before he dies must be for his benefit and not solely to preserve his organs', a principle reiterated when the recruitment strategy of 'elective ventilation' was declared unlawful.[10] Although such principles have theoretically been superseded by the Human Tissue Act, it should be noted that the Act limits interventions to those in the patient's 'best interests' or as part of an approved research project.

'Best interests', the principle governing care of the incompetent adult, has been incorporated into statute under the Mental Capacity Act 2005, and although not limited to medical best interests,[11] has not been explicitly redefined to accommodate this category of intervention. Existing law furthermore, as defined within the Bland case, appears to specifically prohibit the continuation of life-sustaining treatment purely for the benefit of potential organ recipients.[12]

The ICS guidelines on patient testing and continuation of support do not therefore conform to established law and although the Office of the Official Solicitor was represented on the working party, there has not been ratification at governmental level. This shortcoming, particularly the failure to endorse an extended interpretation of best interests, clearly remains a concern and offers a ready argument to those practitioners opposed to implementation for whatever reason.

The other aspect raised in opposition to NHBOD is the nature and timing of death, a concept not formalized under English statute, but compromised by earlier attempts to validate brainstem death as equivalent to cardio-respiratory death, namely: 'brain death represents the stage at which a patient becomes truly dead'.[13] Judicial acceptance of brainstem death followed, and legal commentators currently maintain that brainstem death is the only true death.[14] This creates problems when death has to be certified within a short timeframe to minimize warm ischaemic injury. Although the ICS has adopted the Institute of Medicine protocol of certification after absence of cardio-respiratory activity for 5 min,[15] as opposed to the 2 min stand-off at Pittsburgh,[16] this falls short of the original Maastricht recommendations of 10 min,[17] and it is apparent that practitioners harbour disquiet, quoting the Lazarus phenomenon as one obvious barrier.[4]

The concept of 'irreversibility' is fundamental to a declaration of death by either neurological or cardio-respiratory criteria and enshrined within the Uniform Determination of Death Act, adopted by virtually all American states. Practitioners at Pittsburgh responded to criticism that irreversible loss of either brain or cardiac function would not have occurred at 2 min with the argument that since the patient or family have refused resuscitation, the clinical state is clearly irreversible. As with brainstem death, therefore, cardio-respiratory death has become a medically defined construct directed at retrieval at optimal viability. Medical practitioners may declare context relevant, but the general public could have difficulty accepting that identical physiological characteristics will be the criteria for initiating resuscitation in one individual, but for embarking on retrieval in another. The amplified blurring of these boundaries in uncontrolled donation within emergency medicine should be apparent.[18]

In 2006, a working party was established through the Royal College of Anaesthetists to revise the 1998 'Code of Practice for the Diagnosis of Brain Stem Death' and 'address the diagnosis and certification of death in all situations and to make practical recommendations which are acceptable both to the relatives of the deceased, to society in general and also to the medical, nursing and other professional staff involved'. The group agreed that it was 'important to completely separate the diagnosis and certification of death from anything to do with the issues surrounding organ donation and transplantation' and it will be noted that the definition of cardio-respiratory death is directed towards certification 'without an unnecessary and potentially distressing delay', despite no evidence that this is necessary where organ donation is not a consideration. Although declared that death can be certified 'after 5 minutes of continued cardiorespiratory arrest', there is apparent ambivalence, acknowledging that 'death is a process rather than an event', and characterized by 'irreversible cessation of cardiac and respiratory activity, and, irreversible damage to the vital centres in the brainstem, due to the length of time in which there has been inadequate circulation to the brain'. If 'irreversibility' is the criterion on which death can be certified, it is uncertain why a 5 min timeframe is adopted when in other circumstances an anticipation of recovery after resuscitation is reasonable at this point, and why it should be declared; 'obviously inappropriate to initiate any intervention that has the potential to restore coronary or cerebral perfusion. . .after death has been certified'.

The adoption of the 5 min timeframe may also be considered less than robust when 'it is accepted that further studies are required to help understand the conditions under which cardiac auto-resuscitation (spontaneous re-starting of the heart) may occur and to refine further the

definition of the appropriate time interval between the cessation of cardiorespiratory function and the declaration of death'.

It can be considered therefore that a satisfactory definition of death for the purposes of organ donation after cardiac death remains elusive and given overt disagreement within the medical profession, society must be engaged as to when the clinical features of death are so consolidated that the patient is beyond harm from organ retrieval or preservation techniques.

It is against this background that the recent report of the Organ Donation Taskforce,[5] established 'to identify barriers to organ donation and transplantation and recommend solutions' can be evaluated. It is acknowledged that 'urgent attention is required to resolve outstanding legal, ethical, and professional issues to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice'. It is proposed that 'an independent UK-wide Donation Ethics Group should be established', but it is curious that the ethical dimension of certain recommendations has not been explored, that the report was not placed before profession and public for consultation, and that the report appears to have been accepted by relevant bodies without discussion of those ethical considerations.[19]

Most practitioners will not take issue with the proposals to nationalize, standardize, and improve the numbers and training of donor transplant co-ordinators or to study the apparent discrepancy between donation and demand from people of black and minority ethnic origin. The intention to drive donation numbers by the obligatory early identification of potential donors, utilizing coordinators 'embedded' within intensive care units, potentially playing an 'active role in enhanced donor care', supported by local 'donation champions', represents a significant cultural change with associated ethical implications. Practitioners may reasonably be concerned that such an explicit emphasis on organ donation will undermine a fragile public confidence and amplify either the real or perceived conflict of interest inherent in withdrawal-of-support decisions as a prelude to non-heart beating donation.

Although not denying that a request for organ donation needs to be conducted competently, requiring knowledge, skills, and time, practitioners may also be concerned at the implicit proposal that such requests be made by individuals from the transplant organization with the 'appropriate training', potentially leaving grieving relatives vulnerable to coercion.[20]

To introduce these strategies without resolution of the accepted ethico-legal hurdles, and making donation a statutory Trust target, with chief executive and medical director becoming responsible for performance, overseen by the healthcare regulators, should constitute a serious concern even to those practitioners supportive of NHBOD and will predictably further alienate those who oppose this initiative. The intention to achieve 'refocusing' and drive donor numbers within other hospital areas where critically ill patients are cared for, emergency medicine, high dependency units, and others, appears ambitious without resolution of the concerns of intensivists, given the amplification of these issues within such environments.[18]

This overall approach represents a radical departure from previous donation initiatives, by introducing policing and enforcement of donor recruitment, rather than identifying new donor pools. The paradox of using authority to change staffing and process within intensive care, despite the risk of alienating clinicians and jeopardizing public confidence, whilst persistently failing to resolve the outstanding uncertainties regarding NHBOD, an approach which would engage clinicians, promote public confidence, and predictably increase organ donor numbers, should not go unchallenged.

The intention to next consider presumed consent, strongly supported by the Prime Minister, Chief Medical Officer, British Medical Association and BMJ editorial board,[21] further demonstrates a detachment from fundamental ethical principles, primarily a respect for autonomy, and exposes a belief that the undoubted need of recipients justifies such action by the state. The arguments for and against this strategy have been set out,[22] but readers should be aware that in principle this concept is already formalized in statute, since the Human Tissue Act allows for hospital authorities 'to take steps for the purpose of preserving the part for use for transplantation' without any consent of the next-of-kin. This is a paradox, given that the Act is founded on informed consent in the aftermath of the retained organs scandals, and demonstrates how recipient need creates conflict with primary ethical principles and indeed the task-force recommendation to honour the 'gift of donation'. The greatest concern is that vulnerable public trust in medical decision-making on futility, fundamental in developing non-heart beating donation as the greatest potential donor pool, would be irreparably undermined by such presumption on the part of the state and its employees. It can reasonably be anticipated that intensivists would recognize the harms of such a strategy and resist implementation, with the associated risk of compromising broader support for donation.

The ethically defensible solution lies not in presumed consent, therefore, but in retaining positive consent expressed through the organ donor register after access to full information on the process of heart-beating and non-heart beating donation, including detail on all contentious areas. Valid consent for NHBOD requires explicit political and legal endorsement of the procedures necessary for viable organ retrieval such that a nationally applicable template can be defined as the basis for consent. Although clearly there can be no absolute obligation to read and understand every detail before such consent, the public could reasonably choose to consent to any donation option, or indeed defer decision-making to their next-of-kin. If the consent process can identify a

designated next-of-kin to whom the individual has expressed their wishes with regard to organ donation, it follows that fears over the vulnerability of the next-of-kin to coercion would be ill-founded. In such a system, although conflict of interest may still be present, certain concerns of those practitioners who have opposed this strategy would reasonably be addressed and any persistent individual moral objections would not be a sustainable barrier to implementation, there being an obligation to both inform the next-of-kin of that position and to arrange transfer of care to practitioners prepared to offer the requested process.[23] Seeking the assent of the next-of-kin where the individual concerned has not positively registered for donation will need to be carefully defined in content, style, and discipline of the requestor, to avoid any accusation of coercion, but this task should not be insurmountable.

The polarized debate within the intensive care community on NHBOD should have been identified as strong justification for a radical reappraisal of all facets of organ donation, majoring on public and professional engagement, an approach adopted in other countries.[24] An explicit goal of such an undertaking would have to be endorsement at the highest level for an approach to NHBOD which is based on an expanded interpretation of best interests and contemporary ethical principles of respect for autonomy, beneficence, and non-maleficence.[25] It is in the interests of all parties and of a viable transplantation programme, that these warning signs are recognized before it becomes too difficult to reverse from a strategy of enforcement and presumed consent. The ethical good of both transplantation and genuinely altruistic donation are too valuable and mutually dependent to risk compromising by a potentially detrimental policy. The critical care community has a vital role to perform in supporting those ethical goods of donation and transplantation, while simultaneously guaranteeing the primary goal of intensive care, survival with a return to a meaningful quality-of-life, and retaining guardianship of public confidence. In the light of the above concerns, it is vital that the critical care community demonstrates responsibility and authority in ensuring equipoise between these objectives and defines the support required from the transplant organizations and government to facilitate all classes of altruistic cadaveric donation, rather than having process dictated and ultimately compromised by these bodies.

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