

Growing Concerns about Brain Death and Organ Donation

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INTRODUCTION

In 1968, the 'Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death' published its report on consensus criteria for determining death in patients with beating hearts and on mechanical ventilation in the United States (US)(1). The primary objective of brain-based criteria was to permit clinical transplant programs to recover organs from heart-beating donors. In 1981, The National Conference of Commissioners on Uniform State Laws approved the Uniform Determination of Death Act (UDDA) stating: "[a]n 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. A determination of death must be made in accordance with accepted medical standards(2)". The UDDA provided the legal permission to procure vital and non-vital organs after using only brain criteria to declare death. Clinical guidelines (**Table I**) were established to ensure accurate and uniform medical standards for determining brain death in pediatric organ donors too(3,4).

THE ROLE OF ORGAN PROCUREMENT ORGANIZATIONS

There are 58 organ procurement organizations (OPO) that are authorised to coordinate deceased organ donation within the US(5). OPOs function as private organizations independent of hospitals and operate under a government contract through the Centers for Medicare and Medicaid Services(5). Each OPO is assigned to serve donor hospitals and

transplant centers within a specific geographic area (called donation service area). OPOs provide comprehensive services including: (i) surveillance, evaluation, management, selection, and consent of potential donors, and (ii) preparation, recovery, and transportation of procured organs to transplant centers. Much of the US growth in organ donation rates has coincided with the establishment of the Organ Donation Breakthrough Collaborative through the guidance of the Health Resources and Services Administration of the Department of Health and Human Services in September 2003(6). The Organ Donation Breakthrough Collaborative has set goals for each OPO: 75% donor conversion rate (*i.e.* the percent of potential donors who become actual donors) and an average of 3.75 organs recovered per donor(6).

As early as 1998, in-house and team huddle programs encouraging early involvement of OPO coordinators in patient care as potential donors were promoted to increase organ donation rate in US hospitals(7). In-house and team huddle programs position OPO coordinators as full-time staff in hospitals with high volumes of potential donors(8). OPO coordinators have direct access to adult and pediatric patients and are linked to the medical team responsible for patient care before end-of-life decisions are made. In-house and team huddle programs enable early management of patients as potential donors to preserve organs before brain death declaration and consent for donation(9-11). Families, however, are unaware of this linkage between OPO coordinators and medical teams providing care to patients. These programs were

TABLE I CLINICAL GUIDELINES FOR THE DETERMINATION OF BRAIN DEATH*

A. Clinical criteria

- Unresponsiveness
 - Coma, and
 - Absence of motor responses to pain in all extremities
- Absent brainstem reflexes:
 - Absence of pupillary responses to light and pupils at midposition with respect to dilatation (4–6 mm)
 - Absence of oculocephalic reflex
 - Absence of oculovestibular (caloric) responses
 - Absence of corneal reflex
 - Absence of jaw reflex
 - Absence of facial grimacing to deep pressure on supraorbital ridge, or temporomandibular joint
 - Absence of pharyngeal gag reflex
 - Absence of coughing in response to tracheal suctioning
 - Absence of sucking and rooting reflexes
- Apnea (absence of respiratory drive at a PaCO₂ that is 60 mm Hg or 20 mm Hg above normal base-line values)

B. Additional prerequisites

- Presence of clinical or neuroimaging evidence of acute CNS catastrophe severe enough to explain the condition
- Core temperature greater than 32°C (90°F)
- No drug intoxication, poisoning, or neuromuscular blocking agents
- Absence of systemic arterial hypotension
- Absence of confounding medical conditions such as severe electrolyte, acid-base, metabolic or endocrine disturbances, and
- Interval between two evaluations, according to patient's age:
 - Term to 2 month old, 48 hr
 - >2 month to 1 year old, 24 hr
 - >1 year to <18 year old, 12 hr
 - ≥18 year old, interval optional

C. Confirmatory tests

- Cerebral angiography
 - Electroencephalography
 - Transcranial Doppler ultrasonography
 - Cerebral scintigraphy
 - Term to 2 month old, 2 confirmatory tests (required)
 - >2 month to 1 year old, 1 confirmatory test (required)
 - >1 year to <18 year old, optional
 - ≥18 year old, optional
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**Adapted from the American Academy of Pediatrics, Task Force on Brain Death in Children, and the American Academy of Neurology, Practice Parameters for the Clinical Diagnosis of Brain Death(3,4).*

integrated into 'organ donation best practices' and the 'quality improvement initiative' of the Organ Donation Breakthrough Collaborative(8). The goal of the Organ Donation Breakthrough Collaborative has been re-stated as improving organ donor conversion rates, and not necessarily improving the process of care(12).

MEDICAL AND ETHICAL CONCERNS WITH ORGAN PROCUREMENT PRACTICES

Concerns have been raised about the ethical impact of role of OPOs in advancing organ procurement. The general public's concerns are heightened because of several cases in the lay press of wrongfully declaring death in potential organ donors(13-15). The common theme in all cases was an early linkage of OPO coordinators to the care of potential donors before end-of-life decisions. The medical literature has not fully recognized the impact of early OPO involvement on accuracy of declaring death. For instance, Mathur and colleagues(16) researched death declaration in 142 pediatric patients who were procured as heart-beating donors between January 2000 and December 2004 in Southern California. The authors reported study findings based on the medicolegal standard: "If it's not documented, it wasn't done." Only one of the 294 neurological examinations documented completing all the elements for a clinical diagnosis of brain death (**Table I**). The apnea test was performed correctly in only 37 out of 142 (26%) donors. The time intervals between first (if done) and second (if done) clinical examination for brain death complied with age-specific recommendations in only 21 (15%) donors. Cerebral angiography as a confirmatory test of brain death was performed in 83 (58%) donors. Electroencephalography (EEG) was performed in 29 (20%) donors. Sedative drugs or metabolic intoxicants were not excluded as confounding factors when EEG was used as a confirmatory test. In infants (<1 year), the guidelines for brain death determination require the confirmation by 2 EEGs or 1 cerebral angiography. In 29 infant donors, EEG was performed in 7 (24%), cerebral angiography in 10 (34%), and one or the other in 17 (59%). So, at best, only 59% of infant donors had the appropriate confirmatory tests completed. In donors aged more than one year, EEG

or cerebral angiography is required if the interval of time between 2 clinical brain death is insufficient. However, EEG was done only in 22 (19%), cerebral angiography in 73 (65%), and one or the other in 89 (79%) out of 113 pediatric (>1 year) donors. Therefore, it can be concluded that brain death may have been incorrectly declared in a significant proportion of pediatric donors(16). The clinician's expertise or specialty had no relationship with the completeness of the brain death examinations. Noticeably, the authors revealed that OPO coordinators were involved early in the care of 84% of these cases as potential donors and before the first brain death examination without further elaborating on its relevance!

The relationship between early involvement of OPOs in patient care and the accuracy of declaring brain death in heart-beating donors have not been explored previously. It is also important to point out that early involvement of OPO coordinators has not led to higher accuracy in declaring brain death. In contrast, since the primary interests of OPO coordinators are obtaining consent for donation and procuring transplantable organs expeditiously, their early linkage can influence the process of brain death declaration. The possibility of such influence is supported indirectly by Mathur and colleagues' findings of: (i) substantial abbreviation of time intervals between serial clinical examinations for brain death from age-specific recommendations, (ii) the reduction of elements completed in the clinical examination for brain death, and (iii) non-performance of confirmatory tests for brain death declaration in a significant proportion of pediatric donors(16). The likelihood of incorrect declaration of brain death may increase when the observation time necessary to determine irreversible cessation of brain functions is abbreviated for early organ procurement.

Critics have warned the general public and medical community of unintended negative consequences of in-house and team huddle programs for OPO coordinators on medical care and end-of-life decision-making in adult and pediatric patients(17, 18). OPO coordinators put the team in a conflict of interest since the OPO coordinator's goal is to procure organs while the (appropriate) goal of the

medical team is to serve the best interests of the patient. The case of Zack Dunlap illustrates precisely how early involvement of OPO coordinators could have denied a young adult with a potential for recovery the chance of survival if the decision to proceed with organ procurement is rushed(14). Zack Dunlap was declared brain dead 36 hours after blunt traumatic brain injury and prepared for organ procurement. Zack's family noticed movements in his extremities and subsequently organ procurement was abandoned. Over several weeks, Zack regained full consciousness and complete neurologic functions. Wrongful brain death declaration denies patients and families the right to optimal medical care and exacerbates public distrust in the medical profession. Therefore, it is surprising that Mathur and colleagues(16) supported early linkage of OPO coordinators in the hospital care of potential pediatric donors, despite the possibility of a causal relationship of this to subsequent incorrect declaration of brain death.

HOW ACCURATE ARE THE CRITERIA FOR BRAIN DEATH?

Even when the clinical guidelines of brain death determination are applied appropriately, more than 60% of heart-beating donors may have no or minimal structural damage on brain stem autopsy(19) to verify irreversible cessation of brain stem functions mandated by the UDDA. The absence of neuropathologic findings of brain necrosis can suggest reversible causes of coma or perhaps retained neurologic activity undetected by clinical examination(20). The medical community has repeatedly pointed out flaws in the concept of brain death and the limitations of clinical guidelines used for its determination(21-24). This critical piece of information about controversies in declaring death based on brain criteria is not disclosed to the parents or families when consenting for organ donation(24,25). The medical and legal formulation of brain criteria to declare death has also ignored pertinent social, historical and cultural understandings of death and dying(26). Some parents and families as surrogate decision makers may have ethical, religious, and practical questions concerning the legitimacy of the concept of brain death(27). Religious beliefs of parents often play a

significant role in determining how their dying children are cared for at the end of life(28). Fulfilling the needs of families by providing accurate information should be at least as important as organ donor conversion rates.

LEGAL CONCERNS WITH ORGAN PROCUREMENT PRACTICES

There are also legal ramifications for incorrect declaration of brain death. Accurate reporting of the diagnosis, time, and proximate cause of death is legally required in every decedent. After wrongful declaration of brain death in organ donation, the documentation of the proximate cause of death is incorrect. In a heart-beating organ donor who is wrongfully declared brain-dead, surgical procurement becomes the proximate cause of death. Attempts to expedite organ procurement for transplantation by hastening death are subject to criminal prosecution(29). Nevertheless, in the President's Council on Bioethics discussion of the White Draft Paper on neurological determination of death, transplant advocates, in an attempt to further increase the pool of organ donors, have proposed to broaden the definition to include irreversible brain failure or brain dysfunction(30). Broadening of neurologic criteria for death declaration and inclusion of individuals with neocortical failure and intact brain stem functions (commonly referred as persistent vegetative states) would also require either redrafting the UDDA or legislating physician-assisted death and euthanasia. Physician-assisted death and euthanasia are accepted as end-of-life practices in only few European countries.

GLOBAL CONCERNS

Organizational strategies and procurement programs to optimize the deceased organ donation rates are already effective in several developed countries(31). Nevertheless, socioeconomic disparities (measured by education, occupation, and income) continue to influence inequitable distribution of health care resources and provision of quality medical care in these developed countries(32). The provision of health care including transplantation services can also be predicated on socioeconomic status in developed countries as well as developing countries.

However, adopting strategies and programs to optimize deceased organ retrieval without scientific scrutiny and regulatory oversight can have profound societal implications both in developed and developing countries. Transplantation services are increasingly becoming available mostly at big private hospitals in developing countries like India(33), modelled after for-profit hospitals in developed countries, and only the rich are able to afford them. If OPO programs become active in developing countries, the problem of favoring rich recipients at the expense of poor donors will be exacerbated. Indian media recently reported about some transplantation rackets related to kidney transplants(34). These reports addressed the problems of living donors, but the risk of problems being extended to brain-death donors is also real. Reports of wrongful declaration of death for organ donation highlight serious problems and call for national and global debates to address medical, ethical, legal, and sociocultural ramifications of organ procurement programs on end-of-life care. Finally, further studies are needed to assess the impact of early involvement of OPO coordinators in hospital care of patients as potential donors. Unintended consequences of such involvement may include erosion of best medical care for the patients, lack of transparency and inaccuracy of proximate causation of death in donors who are wrongfully declared dead.

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