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Review article

Scientific, legal, and ethical challenges of end-of-life organ procurement in emergency medicine☆

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ABSTRACT

Aim: We review (1) scientific evidence questioning the validity of declaring death and procuring organs in heart-beating (i.e., neurological standard of death) and non-heart-beating (i.e., circulatory–respiratory standard of death) donation; (2) consequences of collaborative programs realigning hospital policies to maximize access of procurement coordinators to critically and terminally ill patients as potential donors on arrival in emergency departments; and (3) ethical and legal ramifications of current practices of organ procurement on patients and their families.
Data sources: Relevant publications in peer-reviewed journals and government websites.
Results: Scientific evidence undermines the biological criteria of death that underpin the definition of death in heart-beating (i.e., neurological standard) and non-heart-beating (i.e., circulatory–respiratory standard) donation. Philosophical reinterpretation of the neurological and circulatory–respiratory standards in the death statute, to avoid the appearance of organ procurement as an active life-ending intervention, lacks public and medical consensus. Collaborative programs bundle procurement coordinators together with hospital staff for a team-huddle and implement a quality improvement tool for a Rapid Assessment of Hospital Procurement Barriers in Donation. Procurement coordinators have access to critically ill patients during the course of medical treatment with no donation consent and with family or surrogates unaware of their roles. How these programs affect the medical care of these patients has not been studied.
Conclusions: Policies enforcing end-of-life organ procurement can have unintended consequences: (1) erosion of care in the patient's best interests, (2) lack of transparency, and (3) ethical and legal ramifications of flawed standards of declaring death.

Contents

Abbreviations: DHHS, US Department of Health and Human Services; ECMO, extracorporeal membrane oxygenation; HBD, heart-beating donation; HRSA, Health Resources and Services Administration; NHBD, non-heart-beating donation; ODBC, Organ Donation Breakthrough Collaborative; OPO, organ procurement organization; PCB, President's Council on Bioethics; RAPiD, Rapid Assessment of Hospital Procurement Barriers in Donation; UDDA, Uniform Determination of Death Act.

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1. Introduction

Recent advances in transplantation have expanded the criteria of age and end-stage organ diseases of transplant recipients, thus exponentially lengthening the waiting list for new organs.[1] Expanding the pool of recipients has increased the demand for transplantable organs from both living and deceased donors. The explosive growth in organ demand, without a matching increase in supply, has created what many believe is an (inter)national organ shortage crisis. To mitigate this crisis, U.S. hospitals were successful in increasing deceased organ procurement from heart-beating donation (HBD) and non-heart-beating donation (NHBD) despite growing scientific uncertainty about medical criteria and standards for declaring death and procuring organs in both types of donations.[2] The transplantation division in the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services (DHHS) initiated the Organ Donation Breakthrough Collaborative (ODBC) and bundled quality improvement programs promoting them as best donation practices in hospitals.[3] These programs included implementation of (1) team-huddling of in-house procurement coordinators with hospital staff[4] and (2) the Rapid Assessment of Hospital Procurement Barriers in Donation (RAPiD) tool.[5] Both programs were designed to realign hospital policies to maximize access to, and surveillance of, hospitalized critically ill patients who might be potential donors to optimize management for organ preservation and to secure surrogate consent for surgical procurement.[1] The ODBC was a concerted effort of the transplantation community to bring about major organizational and structural changes in hospitals to maximize the rate of procuring organs at the end of life.[6] The ODBC programs were intended to reform the cultural, organizational, and administrative characteristics of hospitals into a favorable environment for maximizing the rate of organ procurement for transplantation at the end of life.[6,7] Similar collaborative programs have been implemented in other countries (e.g., Spain and United Kingdom).[7–9]

Emergency department physicians play a key role in the resuscitation and initial care of critically ill patients, and may be required to participate or collaborate in organ preservation after successful or unsuccessful cardiopulmonary resuscitation of out-of-hospital cardiac arrest,[10,11] multiple traumatic injuries, or acute catastrophic neurological injury.[12,13] In this article, we review: (1) scientific evidence questioning the validity of medical standards for declaring death and procuring transplantable organs in HBD and NHBD; (2) the unintended consequences of regulatory enforcement of ODBC programs in hospitals on the quality of medical care rendered to critically ill patients who may be considered potential donors; and (3) the ethical and legal ramifications of current practices of organ procurement on patients and families.

2. Scientific validity of criteria for declaring death

Human death is a singular phenomenon characterized by irreversible cessation of all vital functions (circulation, respiration, and consciousness). For medical, legal, and religious reasons, certainty is essential when determining death. Over the past 4 decades, the criteria and standards (or tests) of declaring death and procuring organs have been abbreviated gradually expanding the pool of eligible donors (Fig. 1).[14–21]

2.1. Neurological standard for determining death in heart-beating donation

The neurological standard for the diagnosis of irreversible coma with apnea was described in 1968.[16] The term *brain death* was associated with irreversible apneic coma, which is a condition of (limited) life versus death. However, this was soon equated with death itself enabling organ procurement in HBD.[22] HBD avoided warm ischemia and injury to procured organs. Active participation of the transplantation community was instrumental in reclassifying patients in irreversible coma with apnea as dead.[23]

The President's Commission and a medical panel recommended passage of the Uniform Determination of Death Act (UDDA) in 1981.[17] The UDDA states: "an individual who sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brainstem, is dead. A determination of death must be made in accordance with accepted medical standards."[18] The accepted medical standards to ascertain the presence of either circulatory–respiratory or neurological criteria for death must be reliable and concordant with the UDDA. Many countries have similar death statutes.

In 2008 the President's Council on Bioethics (PCB) questioned the scientific evidence for the biological underpinnings of the brain criterion and the neurological standard for declaring death in HBD.[24] Clinical and pathologic observations refute several assumptions about irreversible coma with apnea: (1) somatic integration of biological functions ceases in a living organism; (2) circulatory arrest ensues because of impending cardiovascular collapse; and (3) whole-brain destruction and necrosis (physiological decapitation) is always present.[25] Other clinical observations of patients declared brain dead (Table 1) invalidate the equating of brain death with human death.[26–40] Surgery to procure organs from brain-dead donors is performed without the administration of general anesthesia or analgesic opioids. Nociceptive hemodynamic responses and limb-withdrawal movements in donors during surgery often require suppression by administration of neuromuscular-blocking agents. Thus, one cannot exclude the possibility of nociception during organ procurement. Complex motor responses of limbs in response to nociceptive stimuli in a brain-dead person require brainstem input in addition to intact spinal cord motor reflexes. The accuracy of the clinical diagnosis of brain death in organ donors is also questionable.[41,42] First, donors can retain residual coordinated neurological function. Second, minimal or no brainstem ischemia is observed in more than 60% of donors at autopsy. Third, pathological series examining the spinal cord in brain-dead persons demonstrate upper cervical spinal cord ischemia, suggesting infarction in most (≥50%) cases from direct compression of the cord or its arterial blood supply during cerebellar tonsillar herniation, which is a confounding factor in the clinical examination and diagnosis of unresponsive coma and apnea.[40] Fourth, neither confirmatory cerebral blood flow studies nor neuroelectrophysiological tests are

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mandated for declaring brain death in donors. A high rate of clinical misdiagnosis is reported in other supposedly irreversible states of impaired consciousness or coma.[43] Fifth, there is wide variability in complying with clinical guidelines for declaring brain death at neurological institutions.[44]

Substantial scientific evidence (Table 1) suggests the neurological standard for declaring death in HBD is not UDDA compliant. The neurological standard (loss of consciousness and respiration) fails to fulfill the whole-brain criterion of death that *all functions* have ceased irreversibly.[2] The PCB recommends replacing *brain death* with the term *total brain failure*, a catastrophic neurological state of irreversible coma with apnea.[24] To salvage HBD, the PCB proposes a philosophical rationale for why this neurological state should be considered death: "Living organisms *must*—and *can* and *do*—engage in commerce with the surrounding world". When the innate respiratory drive is lost, this capacity is also lost and the organism should no longer be considered alive. "If there are no signs of consciousness and if spontaneous breathing is absent and if the clinical judgment is that these neurophysiological facts cannot be reversed . . . a once-living patient has now died".[24] The PCB's final conclusion is that this new philosophical rationale upholds the current neurological standard of *total brain failure* (or brain death) as equivalent to human death. Advocates have endorsed the PCB philosophical rationale and its reinterpretation of the brain criterion of death in UDDA.[45] However, a challenge of the philosophical justification for defining living patients on the basis of the critical role of the spontaneous inner drive of breathing has been made on scientific grounds.[46] The inner drive to breathe is absent not only in patients with total-brain failure (or brain-death) but also in conscious patients with lower brainstem lesions and during sleep in patients with Ondine curse (in whom the lack of drive is arguably also "irreversible," insofar as the person will die during sleep, at least without ventilatory assistance).[47] However, to defend the practice of HBD advocates have accepted, without serious scientific or philosophical questioning, the novel reinterpretation of the neurological standard of death.[45,48]

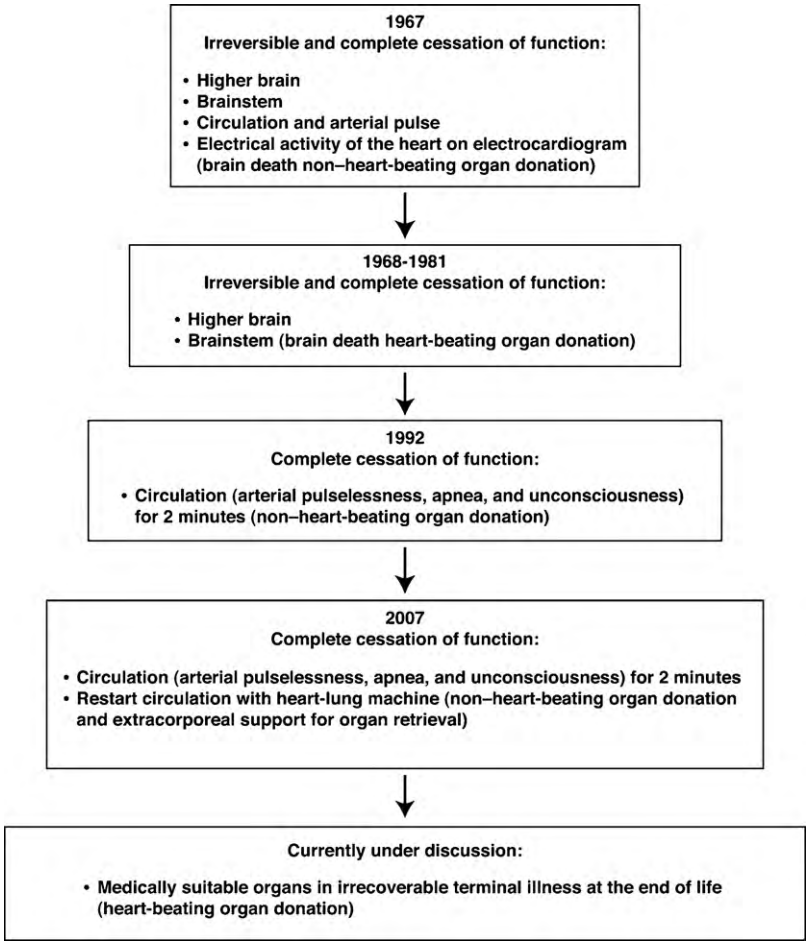

Fig. 1. The abbreviation of criteria and standards for declaring death and procuring organs for transplantation at the end of life over the past 4 decades.
From 1967 to present, the criteria and standards of declaring death in heart-beating and non-heart-beating procurement of transplantable organs have gradually been abbreviated to increase the pool of end-of-life donors.

1967 Starzl[14] and Bernard[15] performed landmark successful cases of liver and heart transplantations, respectively, after using irreversible cessation of both brain and circulatory functions.
1968 The Ad Hoc Committee of the Harvard Medical School developed the brain criteria for human death.[16]
1981 The President's Commission[17] published its report on defining death and on the medical, legal, and ethical issues in determining death; later that same year, the Uniform Determination of Death Act was enacted.[18]
1992 The University of Pittsburgh Medical Center developed the non-heart-beating organ donation protocol to procure organs from the terminally ill who do not fulfill Harvard brain criteria for death before mechanical ventilation is discontinued.[19]
2007 The United Network for Organ Sharing established guidelines for extracorporeal support for organ retrieval in non-heart-beating donation.[20]
Present Under discussion: *The New England Journal of Medicine* roundtable discusses heart-beating organ donation in irrecoverable terminal illness at the end of life.[21]
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2.2. Circulatory standard for determining death in non-heart-beating donation

With the demand for transplantable organs exceeding the number of organs procured from brain-dead donors, an alternative medical standard to declare death on the basis of cessation of circulation was developed at the University of Pittsburgh Medical Center that later became known as the Pittsburgh NHBD protocol.[19] This protocol was developed to procure organs from dying patients not meeting formal brain-death criteria (Fig. 1). The Pittsburgh pro-

Table 1
Contemporary pro and con arguments for equating the neurological standard of death in heart-beating donation and the circulatory standard in non-heart-beating donation with true death in human beings.

	Pros	Cons
Neurological standard for declaring death		
• Irreversible loss of	• Irreversible loss of	• Brain-dead patients maintain and are capable of many human biological functions (e.g., growth, maturation to puberty [children], reproduction, pregnancy, childbirth) that are mediated or coordinated by the brain or the brainstem[35,39]
○ Wakefulness and awareness (i.e., coma)	○ Capacity for consciousness	• Preservation of integrated hypothalamic-endocrine functions[26,39]
○ Motor responses to pain in all extremities	○ Ability to breathe	• Maintenance of stable cardiovascular hemodynamic state [29]
○ Brainstem reflexes	○ "Essence" of being human	• Nociceptive hemodynamic responses, catecholamine release, and limb-withdrawal movements to surgical procurement[27,30,32]
○ Spontaneous capacity to breathe[44]	○ Personhood[22]	• Cerebral functions cannot be tested by clinical examination because the tracts of passage to and from the cerebrum through the brainstem may be destroyed or nonfunctional[36,40]
	• The certainty of impending irreversible cardiovascular collapse and cardiac arrest within hours or days[17]	• Clinical assessment of internal awareness is limited in patients who may otherwise lack the motor function to show their awareness[36,40]
	• The loss of somatic integration of body functions as a living human being[17]	• Uptake of lipophilic radiopharmaceuticals by viable cerebral cortex neurons[38]
	• Futility of further aggressive medical treatment[16]	• Presence of residual electric cerebral activity on electroencephalogram[28]
	• Whole-brain necrosis (i.e., physiological decapitation) is always present[17]	• Presence of auditory or somatosensory evoked potentials[31]
	• Living organisms cannot conduct commerce with the surrounding world once the innate respiratory drive and the capacity to breathe are lost[24]	• Incidence of high cervical spinal cord ischemia early during intracranial hypertension[40]
		• "Brain-dead" patients have stereotyped complex movements, presumed to be spinal cord responses, that may originate in the brainstem[33,34]
		• Clinical tests to confirm complete and irreversible cessation of whole-brain or brain-stem functions do not have the reliability or accuracy to declare brain death with certainty[41,42]
		• Brain autopsy reveals no or minimal structural damage to critical brain structures such as the brainstem in organ donors declared "brain dead"[37]
		• Innate respiratory drive is absent in conscious patients with lower brainstem lesions and during sleep in patients with Ondine curse[47]
Circulatory standard for declaring death		
• Circulatory arrest [68]	• Spontaneous autoresuscitation in human cases (1912–1972) unlikely after 65 s of circulatory arrest[51]	• Spontaneous autoresuscitation after 10 to 15 min of circulatory arrest (1982–2007) after termination of human cardiopulmonary resuscitation[57]
○ Loss of systemic arterial pulse for 2 to 5 min	• Intent and action of not resuscitating with current medical technology[45,74]	• Spontaneous recovery of electrocardiographic activity after 10 min of mechanical asystole [70]
○ Cardiac mechanical asystole (echocardiography) for 2–5 min	• Patient or surrogate consent needed for do-not-attempt-resuscitation order and for donation of transplantable organs[45,73]	• Recovery of neurological functions after periods of prolonged circulatory arrest in hypothermia or drug intoxication[66,67]
○ Preserved electrocardiographic activity		• Preservation of cerebral activity on electroencephalogram after 3 min of complete circulatory arrest[58]
		• Hearts procured after circulatory arrest recover normal mechanical and electrical activities in transplant recipients[54,69]
		• Initiation of cardiopulmonary bypass after circulatory arrest for interval support and organ preservation lead to spontaneous recovery of neurological and cardiac functions in donors requiring mechanical and pharmacological suppression[61]
		• Circulatory vascular tone maintains coronary and cerebral perfusion pressures and can recover functions after diastolic (asystolic) perfusion pressure as low as 15 mmHg[71]

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tocol defined the circulatory standard for declaring death by the loss of arterial pulse and circulatory arrest for 2 min. This protocol laid the groundwork for the Institute of Medicine (IOM) to legitimize procuring transplantable organs from patients not declared brain dead.[49] The IOM expert panel endorsed the circulatory standard of the Pittsburgh protocol and concurred that there was a zero chance of autoresuscitation (spontaneous recovery of heart and brain function) after 65 s of mechanical asystole or lack of arterial pulse.[50] The scientific support for this standard emanated from an analysis of published (1912–1970) case series.[51] In a retrospective analysis of 12 donors in NHBD, spontaneous circulation never resumed after >1 min of absent circulation, suggesting that 2 min of absent circulation is sufficient to exclude autoresuscitation with scientific certainty and certify death.[52] However, to exclude the likelihood of an autoresuscitation event at a rate of 1 per 1000 donors with a probability of less than 5% (type I error) and a power of 80% (type II error), it is necessary to document zero cases of auto-resuscitation in >10,000 patients.[53] Nevertheless, the Pittsburgh NHBD protocol became the template for NHBD protocols for procuring transplantable organs (including hearts).[54] Transplantation professionals were influential in defining the standard for declaring death in NHBD so as to procure organs before the onset of warm ischemic injury.[55] Variable (75 s to 5 min) cardiac mechanical asystole (or lack of arterial pulse) quickly became the US standard for circulatory declaration of death in NHBD.[56]

Substantial evidence suggests that both the criterion and standard for declaring circulatory–respiratory death in NHBD are not UDDA compliant (Table 1). The circulatory standard of mechanical asystole (lack of arterial pulse) fails to meet the criterion of *irreversible* cessation of circulation and respiration in NHBD. Donors enrolled in NHBD may have normal brain function before mechanical asystole and the declaration of death.[20] The human brain is capable of retaining and recovering integrated neurological functions after 15 min of circulatory arrest or mechanical asystole.[17] Other cases of autoresuscitation—also called the Lazarus phenomenon—have been reported (1982–2006) that describe the delayed spontaneous return of intrinsic circulation after cessation of cardiopulmonary resuscitation and the recovery of integrated neurological functions after longer durations of circulatory arrest.[57] Brain electrical activity and clinically undetected integrated brainstem functions can return despite circulatory arrest. Sharp increases in brain electrical activity on continuous electroencephalogram of dying persons are observed for several minutes after complete cessation of circulation.[58] Yet under current NHBD guidelines, such persons could be donors and have their organs surgically procured.[54]

The notion of irreversibility of the circulatory standard for declaring death and procuring organs was scientifically challenged in 2007 when the Organ Procurement and Transplantation Network decided to include extracorporeal membrane oxygenation (ECMO) and bronchoscopy as donation-related procedures in NHBD (Fig. 2).[20] Such donation-related procedures can reverse the conditions that meet the standard used for declaring circulatory death during organ-procurement surgery.[59] Artificial support of circulation with cardiopulmonary bypass and reintubation for lung ventilation can resuscitate these patients during organ procurement. Resuscitated patients who are donors then require pharmacological agents and/or thoracic-aortic balloon-occlusion of coronary and cerebral circulation to suppress the spontaneous return of cardiac activities and neurological function.[60,61] Studies have shown the effectiveness of ECMO and cardiopulmonary bypass in eliciting the return of full neurological functioning after prolonged refractory circulatory arrest,[62–65] which attests to the resilience and capacity of the human brain to recover after circulatory arrest.[66,67] The use of ECMO makes the conclusion even more likely that patients enrolled in NHBD are not dead at the time of organ procurement.

At a national transplantation conference, NHBD was renamed "donation after cardiac death" to promote the perception that organs are donated after death.[68] Since normal-beating hearts are also being harvested for transplantation, the IOM recommended changing "donation after cardiac death" to "donation after circulatory death" to avoid confusion.[45] However, this nomenclature change has escaped appropriate scientific scrutiny and analysis of the standard for verifying true physiological cessation of circulatory and respiratory functions and for determining death. Hearts recovered in NHBD have normal native mechanical and electrical functions after transplantation.[54,69] Mechanical asystole is therefore reversible and should not be accepted medically or legally as the standard for determining cardiac or circulatory death.[21] In addi-

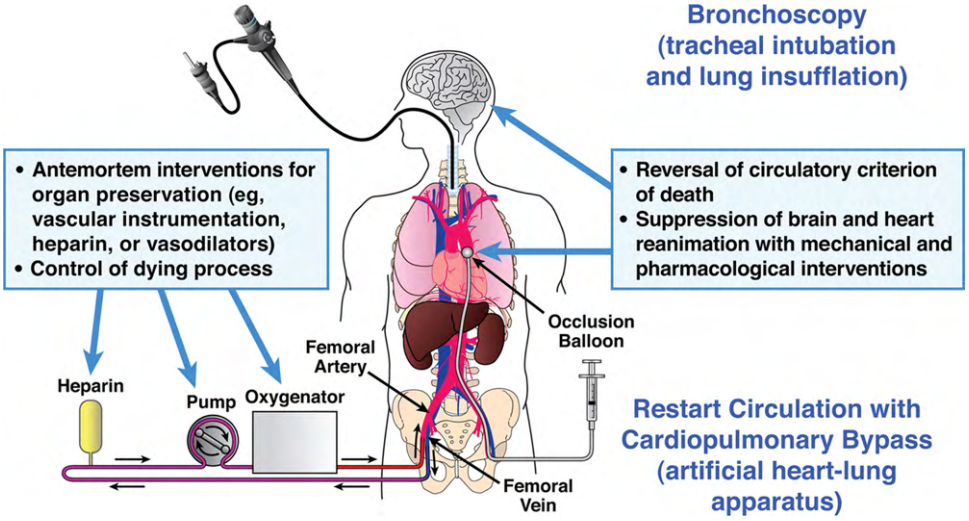

Fig. 2. Organ-donation-related procedures for temporary organ preservation in non-heart-beating donation. The Health Resources and Services Administration of the US Department of Health and Human Services and the Organ Procurement and Transplantation Network include extracorporeal membrane oxygenation with a cardiopulmonary bypass machine (artificial heart-lung apparatus) and bronchoscopy as donation-related procedures for organ preservation in donation after cardiac death.[20] The use of a cardiopulmonary bypass machine (artificial heart-lung apparatus) is initiated for the artificial circulation of oxygenated blood necessary for organ preservation, which reverses the circulatory criterion of death. Tracheal intubation and lung insufflation are required for bronchoscopy. (Reprinted with permission from Springer Science and Business Media.[59])

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tion, spontaneous recovery of electrical activity of the heart muscle after asystole can occur after 10 min of circulatory arrest.[70] Since death is a singular phenomenon, the physiological parameter of circulation must be included in any standard. Circulatory vasculature tone maintains diastolic and perfusion pressures for the physiological function of vital organs.[71] The brain and heart can continue functioning with perfusion pressures as low as 15 mmHg. For uniform determination of death, loss of circulatory vascular tone and asystolic pressure below the minimum are necessary for a sufficient time for all organ function to cease. For the standard to be medically acceptable, the UDDA requires that it fulfills the criterion of irreversibility.

In view of the growing scientific scrutiny of NHBD, advocates have been compelled to reinterpret substantively the UDDA statutory language of circulatory–respiratory criteria of death on philosophical grounds.[45,72] Since the circulatory standard of death in NHBD fails the UDDA criterion of *irreversibility* of cessation of respiratory (brainstem) functions and circulation, advocates have argued that the UDDA meaning of "irreversible" is "permanent".[45,73,74] For determining death, they redefine their own understanding of "permanence" (i.e., will not restore native vital functions spontaneously or because of intent and action not to resuscitate with currently available technology) and "irreversibility" (i.e., cannot restore native vital functions by resuscitation with currently available technology).[45] Thus, they posit permanence as having the intended meaning of irreversibility under the UDDA. But by that definition, the ceased vital functions can be reversed. Did the President's Commission intend for "irreversible" to have different meanings within the UDDA when determining death by a circulatory standard versus a neurological standard? The commission's report used the words *irreversible* and *permanent*.[17] Wherever permanent was used, it was followed by a description of loss of function that *cannot recover because of ischemia, damage, destruction, or necrosis*. Neither *intent nor action not to resuscitate* was mentioned as a contingency qualifying permanent as irreversible. However, the novel definition set forth masks undisclosed intent to recover transplantable organs and action to begin surgical procurement before legal death.

Reinterpretation of UDDA statutory language in NHBD is crucial to maintain public trust in organ donation and transplantation. However, the reinterpretation of UDDA and what constitutes human death in transplantation practice has not been subjected to wide public debate nor has broad consensus been reached on it.[75] Nevertheless, the UDDA wording had consensus agreement from the American Bar Association, the American Medical Association, and the National Conference of Commissioners on Uniform State Laws.[17] If the contingency of "intent and action not to resuscitate" is rejected in defining death, then the procurement of transplantable organs becomes a life-ending intervention.

3. Collaborative programs for organ procurement

3.1. The role of procurement coordinators

The ODBC has designated 58 organ procurement organizations (OPOs) authorized to coordinate deceased organ donation within the United States.[76] OPOs function as private organizations independent of hospitals and operate under a government contract through the Centers for Medicare and Medicaid Services.[77] Each OPO is assigned to serve donor hospitals and transplant centers within a specific geographic area (i.e., a donation service area). OPOs provide comprehensive services, including (1) surveillance, evaluation, management, selection, and consent of potential donors; and (2) preparation, recovery, and transportation of procured organs to transplant centers. The ODBC has set 2 goals for each OPO: a 75% donor conversion rate (i.e., the percentage of potential donors who become actual donors) and an average of 3.75 organs recovered per donor. Regulatory agencies have endorsed the ODBC and these goals as "organ donation best practices" and have mandated their adoption as a quality improvement initiative.[7] The primary goal of the ODBC has been restated as improvement of organ donor conversion rates, which does not necessarily improve the process of end-of-life care of hospitalized critically ill patients or their families.[78] In synchrony with this goal, a pilot study has suggested that improvement in consent rates for organ donation by patients and/or families requires that they be approached in the emergency department when medical treatment is being sought.[79] National programs of procurement coordinators maximize end-of-life organ procurement in other countries e.g., Spain and United Kingdom.[7–9]

3.2. Team-huddle of procurement coordinators with hospital staff

As early as 1998, in-house and team-huddle (also known as collaborative partnerships) programs to encourage the early involvement of procurement coordinators in patient care for the recruitment of potential organ donors were being promoted to increase donation rates in US hospitals.[3] The programs position full-time OPO staff as procurement coordinators in hospitals with a high volume of potential donors.[4] Procurement coordinators are then linked to medical teams including emergency, trauma, and critical care physicians, nursing staff, and allied health care staff responsible for direct patient care in a process referred to as a team-huddle. Team-huddling is triggered from the moment a potential donor candidate arrives in the emergency department and remains active throughout the entire hospital course until either death or organ procurement (Fig. 3). Candidates include critically ill adult and pediatric patients with medically suitable organs soon after arrival in the emergency department who have been resuscitated and remain on mechanical ventilation and/or are admitted to a critical care unit.[80]

Procurement coordinators, as collaborative partners, have unrestricted access to critically ill patients, which enables the identification and preemptive management of potential candidates as organ donors before brain death is declared or surrogate consent for HBD is obtained.[81,82] They also have access to critically ill patients who may be potential candidates in NHBD during the course of medical treatment before the salvageability of patients with potentially life-threatening illness or unrecoverable conditions has been determined (Fig. 3). A timely access of procurement coordinators to potential candidates with catastrophic brain injuries can facilitate conversion from NHBD to HBD. Those potential candidates who retain some brainstem reflexes are resuscitated without treating intracranial hypertension until they progress to brain death.[83] HBD has higher yield and better quality organs for transplantation than NHBD. Families are usually not aware of the collaboration between procurement coordinators and hospital medical teams and are not informed of treatment strategies inducing brain death in potential candidates to increase the organ yield per donor.

The early linkage during initial resuscitation and subsequent inpatient treatment, combined with a lack of standard guidelines for declaring patients unrecoverable soon after an acute life-threatening illness or trauma, can lead to misguided aggressive resuscitation to preserve organs instead of save patients' lives.[84] Determining the patient's potential for recovery with reasonable accuracy and certainty soon after successful resuscitation can also be difficult after neurological injury or coma due to traumatic injury, out-of-hospital cardiac arrest, or acute neurological events.[85] Procurement coordinators may also engage, as part of the medical team, with families regarding end-of-life decisions. As

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a prelude to organ donation, do-not-attempt-resuscitation orders are often implemented if the patient is determined to have suffered unrecoverable neurological injuries or coma. In 1 study, substantial variations in the timing of do-not-attempt-resuscitation orders across hospitals in the national trauma registry were explained not by patient characteristics but instead were associated with institutional differences in end-of-life ethos and perceptions of the ability of patients to recover from life-threatening traumatic injuries.[86] A precipitous change in the focus and goal of medical treatment, from saving lives to preserving and procuring transplantable organs, may deny patients with survivable injuries the chance of recovery; it may also influence the quality of the end-of-life care rendered to those who have been deemed not recoverable. Organ donor management pathways breach more than 60% of the national quality indicators for end-of-life care offered the terminally ill.[87]

We have argued that early interjection of procurement coordinators into the medical care of potential donors may influence compliance with clinical guidelines for the neurological declaration of death and therefore may raise doubt about the accuracy of the diagnosis of brain death in donors.[88] Poor compliance with the clinical guidelines has been reported in many neurological institutions when brain death has apparently been declared for purposes of organ procurement.[42,44] Institutionally using the team-huddle or collaborative approach to care for critically ill patients, who may be potential candidates for either HBD or NHBD, will inevitably confuse the situation by bundling what is in the patient's best interests (i.e., delivery of appropriate medical care) with the procurement coordinator's primary interest (i.e., securing consent to donate and expeditiously procuring transplantable organs).

3.3. The RAPiD program

The RAPiD program is being implemented in US hospitals to enhance the continuous quality improvement and operational effectiveness of hospital organ donation processes.[5] Its objectives are to identify and overcome barriers to donation at US hospitals. Such barriers principally include the diversity of attitudes, beliefs, values, cultures, and knowledge of the hospital staff (i.e., physicians, health care providers, and hospital administrators) about organ donation processes and procurement policies and procedures. RAPiD measures the extent of compliance by hospital staff with procurement policies and procedures; it recommends implementation of "corrective" interventions to change attitudes and behaviors deemed necessary to improve the rate of organ procurement; and it raises the possibility of future punitive action against hospitals assigned a poor rating. To create greater compatibility with national strategies that maximize organ procurement, RAPiD realigns the psychosocial characteristics of the hospital staff's knowledge of and adherence to policies about donation, patient advocacy, and the hospital–OPO relationship.

The implementation of RAPiD has served to dismantle the safeguards and boundaries put in place to protect the rights of patients, families, health care providers, and physicians. The use of qualitative methods to measure legitimately held attitudes and beliefs about procurement policies and processes, with the goal of "correcting" those attitudes, would stifle valid opposition and perpetuate the assumption that current procurement policies and processes are medically necessary, morally appropriate, and socially desirable. Thus, RAPiD has become the tool that ODBC uses to force donation best practices on hospital staff through hospital

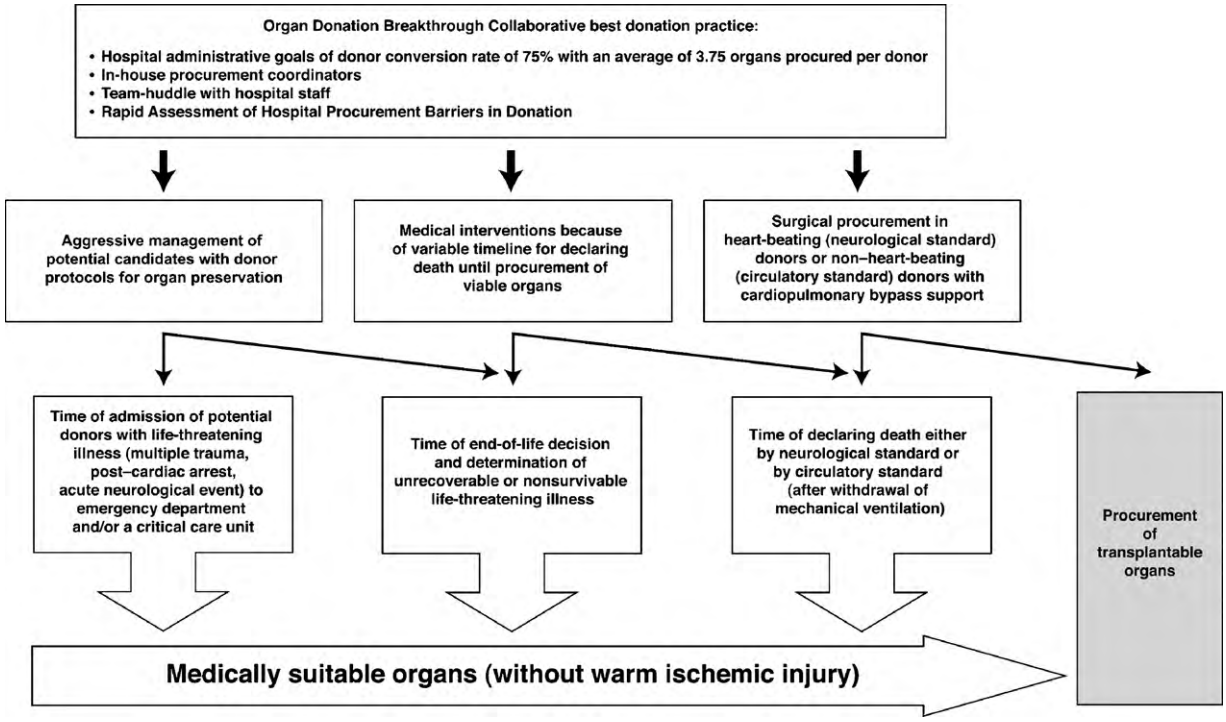

Fig. 3. Organ donation breakthrough collaborative, best practices in organ donation, and timeline for patient care until surgical procurement.
The Organ Donation Breakthrough Collaborative (ODBC) has set hospital goals of a 75% donor conversion rate (i.e., the percentage of potential donors who become actual donors) and an average of 3.75 organs recovered per donor.[3] A team-huddle of in-house procurement coordinators with hospital staff is triggered from the moment of arrival of potential donors with life-threatening illness (e.g., multiple trauma, post–cardiac arrest, acute neurological event) to the emergency department during initial resuscitation and/or treatment in a critical care unit with no consent to donate organs or knowledge of consent or its lack by families or surrogates.[4] Potential donors are critically ill adult or pediatric patients with medically suitable organs who are on mechanical ventilation. Donor management protocols of the ODBC can influence the timeline and type of medical interventions at three critical times: arrival in the emergency department, end-of-life decision making, and declaration of death either by neurological or by circulatory criteria (i.e., after withdrawal of mechanical ventilation) for heart-beating or non–heart-beating organ procurement. Surgical procurement with cardiopulmonary bypass may be initiated in non–heart-beating donors to minimize warm ischemic injury to procured organs.[20] The Rapid Assessment of Hospital Procurement Barriers in Donation seeks to increase hospital staff compliance with ODBC procedures and protocols outlined in hospital policies.[5]

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policies. In that respect, RAPiD and its subsequent hospital policy implications may contravene the conscience clause that allows hospital staff to opt out because of personal ethical, moral, or religious convictions.

4. Ethical and legal implications of declaring death for organ procurement

4.1. Ethical implications

Scientific flaws in declaring death for organ procurement have ethical implications for potential donors, their families, physicians, and health care providers. For the purpose of organ procurement in HBD, a paradoxical death (i.e., brain death) is declared despite the physical image of a functioning body, which is contrary to conventional opinion and scientific evidence. Family members and health care professionals may experience adverse emotional and cognitive conflicts about having to participate in a declaration of paradoxical death followed by feelings of guilt or second-guessing of their actions.[89] Severe psychological sequels of depression, anxiety, and posttraumatic stress disorder have been reported, and these conditions can complicate the grief reactions of family members of deceased donors.[90] Physicians and health care providers may even experience moral distress from being part of a practice in which they perceive the procurement of organs as an act of euthanasia.[91] Hospitals are then confronted with conflicting interests and roles: providing appropriate end-of-life care for patients in the best interests of the patients and their families or else complying with regulatory policies that view patients as potential donors and sources of transplantable organs.

The argument that declaring death for organ donation should be contingent on *an intent and action not to resuscitate* provides false moral certitude that organ-procuring practices are consistent with processes occurring after death. Monotheistic religions share basic tenets about the sanctity of life and forbid ending a life to recover organs.[59,92] Scholars have not reevaluated the growing scientific uncertainty about which criteria constitute a prerequisite for a declaration of death before organs can be procured nor have they reexamined the moral judgment that a living human being who is either brain-dead or at the end of life is “as good as dead” for purposes of organ procurement.[53,93] Scholars must ask whether there is harm to potential donors and their families if death is arbitrarily redefined in order to allow the procurement of human organs.

4.2. Legal implications

State and federal judicial systems are the designated authorities for interpreting statutes. When transplantation advocacy groups and private professional organizations arbitrarily preempt this role, there can be serious consequences. Thus, transplantation advocates who set themselves up to interpret laws governing the definition of death and how it is declared[45] are implicitly reaffirming that organ procurement occurs in living individuals who are declared dead according to convenience criteria established to maximize organ procurement. In current HBD and NHBD protocols, organs undergo de facto procurement before legal death actually occurs.[94,95] Current US laws prohibit death due to or by consent for organ procurement. Commentators have argued the non-compliance of clinical guidelines for organ donation with the death statutes in other countries too, such as Australia and Canada.[2,96,97] Despite evidence that organ procurement and resuscitation for organ preservation are inconsistent with death statutes, governmental policies are implemented enforcing this practice.[9,20]To address the ambiguity and uncertainty of determining death in donors, the construct of end-of-life organ donation has to be revised. First, the medical profession and society must abandon the legal and moral fiction that the current practice of organ procurement in either HBD or NHBD is compliant with the dead donor rule. At a minimum, prospective donors and/or surrogates must be fully informed of the scientific and medical doubts about declaring death when consenting for HBD or NHBD. Second, we have argued elsewhere that continued practice of procuring transplantable organs must include: (1) societal agreement on abandonment of the dead donor rule, (2) legislative revisions reflecting abandonment of the dead donor rule, and (3) requirement of mandated choice to donate organs (an individual must choose between 2 options before death: agreement or refusal to donate organs).[98] Mandated choice ensures that a person’s decision to participate in end-of-life organ donation is made in compliance with the societal values of respect for autonomy and self-determination. However, there has been neither public discussion nor agreement on abandoning the dead donor rule to legitimize current practices. Instead, few have suggested further revision of procurement practices by permitting organ procurement before death in the operating room with general anesthesia after a surrogate has consented for withdrawal of life support and organ donation.[99,100] The transplantation community continues to defend current practices exclusively on utilitarian grounds (i.e., saving lives of transplant recipients) despite scientific doubts about the death criteria. This defense implicitly sanctions utilitarian medical homicide. The broader international medical community should take the responsibility of scrutinizing legal, ethical and cultural ramifications of current procurement practices to preserve societal trust in the integrity of the medical profession.

5. Summary

Scientific evidence undermines the biological criteria that underpin the medical practice of procuring organs in HBD and NHBD. The neurological and circulatory–respiratory standards for declaring death are now being articulated on weak philosophical instead of biological grounds. No public or medical consensus exists on the philosophical reinterpretation of death statutes in the United States and other countries. Organ procurement, as an active life-ending intervention, creates ethical and legal challenges to potential donors, families and hospital staff. The impact of collaborative programs on the clinical course and quality of medical care of the critically and terminally ill patients has not been studied.

Conflict of interest

The authors have no affiliation or financial involvement to disclose with any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript. The authors declare that they have no competing interests.

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