ABSTRACT

In 1981 the United States Uniform Determination of Death Act (UDDA) expanded the legally recognized forms of death to either (1) the irreversible cessation of circulatory and respiratory functions, or (2) the irreversible cessation of all functions of the entire brain. The second and new definition is most commonly referred to as death by neurological criteria or brain death. Both cardiopulmonary and brain death are intricately linked to organ transplantation, and the supply of organs. In the US, donation after brain death is the source of the majority of organs. It is also more likely to result in multiple transplantable organs from a single donor, and is currently the only dependable source for heart transplants. Since the UDDA, the legal definition of death has remained unchanged, but there continues to be public and academic controversy regarding the processes surrounding death and organ transplantation. The history of the legal and ethical determination of death is deeply intertwined with the history of organ procurement and transplantation and these interdependent processes result in medico-legal inquiries in addition to a variety of organizational and clinical ethical considerations. Some specific considerations include societal and organizational constitution of death, the public perception of death and the role it plays in defining death, and the role of organ donation and procurement with the withdrawal of life support.
**Introduction**

The United States Uniform Determination of Death Act (UDDA), enacted in 1981, expanded the legally recognized forms of death to either the irreversible cessation of circulatory and respiratory functions, or the irreversible cessation of all functions of the entire brain. The latter was the latest addition and is most commonly referred to as death by neurological criteria or brain death. The definition and implementation of death by neurological criteria came from years of evolving advancements in medicine, law, and research.

The concepts of cardiopulmonary and brain death are intricately linked to organ transplantation. Organ transplantation is dependent on the supply of organs and while living donors are possible for certain solid organs, in the US most organs come from donors after cardiac and brain death. Donation after brain death is the source of the majority of viable organs transplanted as it is more likely to result in multiple transplantable organs from a single donor, and is currently the only dependable source for heart transplants (McKeown, Bonser, & Kellum, 2011). Organs procured from donors with death by neurological criteria are less likely to be damaged from warm ischemia seen with cardiopulmonary death, thus outcomes in recipient patients post-transplantation are better (Watson, & Dark, 2011). Procurement of organs after the death by neurologic criteria occurs while the donor remains on the ventilator with a spontaneous beating heart, and in the medical literature is sometimes referred to as heart-beating donors after brain death.

Since the UDDA, the legal definition of death has remained unchanged, but there continues to be public and academic controversy regarding the many of the processes surrounding death and organ transplantation. The history of the legal and ethical determination of death is deeply intertwined with the history of organ procurement and transplantation. These interdependent processes result in medico-legal inquiries in addition to a variety of organizational and clinical ethical considerations. This paper will discuss societal and organizational constitution of death, the public perception of death and the role it plays in defining death, and the role of organ donation and procurement with the withdrawal of life support.

**History**

**Death by Neurologic Criteria**

Before 1981, the sole standard of death was cardiopulmonary death, which is defined as the irreversible loss of heart and lung function. This standard remained the sole mechanism of recognized death, even in brain injured patients, as irreversible loss of all neurologic function was followed by cessation of breathing and resulted in cardiopulmonary death. In the late 1950s, the development and utilization of the mechanical ventilator allowed physicians to support physiologic function in brain-injured patients and circumvent cardiopulmonary death. During this time there were multiple cases published describing individuals with severe irreversible brain injury, kept alive by mechanical ventilation (A Definition of Irreversible Coma, 1968).

The advent of brain injured patients avoiding cardiopulmonary death on mechanical ventilation was a catalyst for the assembly of an Ad Hoc Committee of the Harvard Medical School, who came together and published a set of guidelines in 1968. These guidelines, titled “A Definition of Irreversible Coma,” set out to define irreversible coma, along with clinical guidelines for its diagnosis, and concluded that irreversible coma should be considered “a new criterion for death” (A Definition of Irreversible Coma, 1968). The publication of these guidelines, now commonly referred to as The Harvard Criteria, were influential leading several US states to begin to develop laws permitting physicians to declare brain injured patients on mechanical ventilators to be dead based on the absence of brain function. Despite the adoption by many states, not all states included this definition of death. This created legal ambiguity, and for a period of time, the same individual could be legally dead in one state and alive in another (Linden, 2009).

The lack of standardization prompted the US President’s Commission for the Study of Ethical
Issues in Medicine and Biomedical and Behavioral Research to address death by neurologic criteria. In 1981, the President's Commission largely endorsed The Harvard Criteria and agreed that patients with lack of brain function should be considered to be dead (U.S. President's Commission, 1981). The President's Commission was also instrumental in developing the UDDA which also in 1981 defined death as either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the entire brain, including the brain stem. After the UDDA, all 50 states subsequently adopted the same definition. The President's Council on Bioethics reaffirmed the use of death by neurologic criteria as a criterion for human death in 2008 with the publication of the white paper on controversies in the determination of death (President's Council on Bioethics, 2008).

Outside the US, most countries have a legal mechanism to declare death by neurologic criteria. There is no international consensus and in the US the definition requires cessation of all functions of the entire brain, while in the United Kingdom the definition requires only brainstem death. Driven by demand for international consensus, a working group, in collaboration with the World Health Organization, is currently developing international consensus guidelines for the determination of death (Shemie, et al., 2014).

Organ Transplantation
The determination of death is deeply entwined with organ procurement and transplantation. Around the time of the development and utilization of the mechanical ventilator, which circumvented cardiopulmonary death in brain injured patients, the first successful transplantation of an organ, a kidney, occurred in 1954. For the first time doctors at Brigham Hospital documented the successful transplantation of a kidney between living identical twin brothers. The procedure was successful and the recipient survived eight years with an intact renal allograft and no evidence of rejection before dying of cardiovascular disease. In 1968, the Uniform Anatomic Gift Act legalized organ donation for transplantation. It took decades for successful heart, lung, and other solid organ transplantation to follow and success required technological advances, the discovery of tissue typing, and the development of immunosuppressive regimens to improve solid organ recipient survival. In 1984, the National Organ Transplant Act prohibited the selling of organs and in 1986 United Network for Organ Sharing (UNOS) received federal funding and support to ensure equitable access and organ allocation and oversight of procurement programs and transplant centers (Linden, 2009).

Initially the earliest kidney transplants came from living donors given the lack of refined tissue typing and immunosuppression. It was the Uniform Anatomic Gift Act that made it legal to donate a deceased person's organs and tissues for transplantation. This was the legislative complement of the Ad Hoc Committee of the Harvard Medical School that set out clinical guidelines for the diagnosis of brain death, both created in 1968 (Linden, 2009).

During this same time, an ethical construct, the “dead-donor rule” was formulated and states that organ donors must be dead before procurement of organs begins and that organ procurement itself must not cause the death of the donor (Truog & Robinson, 2003; DuBois, 2002; Veatch, 2003). The dead-donor rule was based on the widely held ethics principle that it is wrong to kill one person to save the life of another, leading to the conclusion that people should already be dead before vital organs are removed. In ethics literature, the dead-donor rule has been described as "a centerpiece of the social order's commitment to respect persons and human life" (Veatch, 2003). The dead-donor rule has a role in preserving public trust in both the medicine and organ transplantation establishments, and this trust is vital to preserve the voluntary, opt-in system of organ donation in the US (Bernat, 2013).

By the 1980s increased survival rates led to rapid expansion of the organ transplantation field and organ demand outpaced supply. This also included heart transplantation, which is largely dependent on
heart-beating donors after brain death for recipient transplantation success. This has generated increasing demand for organs from "a living body, yet a dead donor," or heart-beating donors after brain death (Greenberg, 2001). It has also increased the pressure for "opt-in" policies to shift to "opt-out" policies.

**Stakeholders**

**Organ Recipients**
Currently there are 121,530 people registered on the organ transplant waiting list. In the US, on average each day, 79 people receive organ transplants and 22 people die waiting for transplants. In 2015, 30,973 people received organ transplants. Between the years 1988 and 2006 the number of transplants doubled, but the number of patients waiting for an organ grew six fold (U.S. Department of Health & Human Services, 2016).

**Organ Donors**
Currently, more than 120 million people in the US are signed up to be organ donors. In 2015, there were 15,064 total donors, over 9,000 of whom were deceased donors (U.S. Department of Health & Human Services, 2016). The process of becoming an organ donor in the US involves opting-in via state registry, through an advanced directive or driver's license, or after individual authorization. Authorization can also be obtained from an individual's next of kin or power of attorney if the individual lacks capacity. It is important to note that US policy requires authorization rather than informed consent for organ donation (Iltis, 2015).

**Oregon Health and Science University**
OHSU's adult determination of brain death policy, defines brain death as the irreversible loss of function of the brain, including the brainstem. OHSU requires two separate physicians to declare brain death. One must be an attending physician and the second, confirming physician must be a postgraduate year two or higher. Of note, two separate exams are not required and may be completed separately or jointly. At OHSU there is no determined physician specialty to declare brain death (OHSU Policy Manager: HC-PC-122-POL).

In regard to organ and tissue donation, the policy is to notify the Pacific Northwest Transplant Bank (PNTB), who serves as the organ procurement organization, when there is any neurologically injured, ventilated patient that has a Glasgow Coma motor score of 5 or less, in the absence of neuromuscular blockade, and prior to the withdrawal of support. Upon declaration of brain death, if the patient is not already a designated donor, PNTB determines medically suitability and will offer the legal next of kin the option of consenting to donation (OHSU Policy Manager: HC-RI-123-POL).

The OHSU policy on organ and tissue donation after cardiac death, states the intent to facilitate organ and tissue donation by offering the option to families. The option of organ donation after cardiac death has become possible in select circumstances when the death and withdrawal of life support is imminent, but the patient has not been declared brain dead. The patient care team will perform withdrawal of life support and the organ procurement organization does not participate in the decision or the withdrawal of life support. The pronouncement of cardiac death shall be the responsibility of the attending physician or designee. Organ donation after cardiac death requires determination of death in a timely manner in order to preserve the viability of the donated organs. In this case, the diagnosis of death will be made by two criteria: (1) absence of heart function for the duration of two minutes as measured by zero pulse pressure as determined by arterial catheter and (2) associated unresponsiveness and apnea (Bernat, 1999).

**Organizational and Clinical Ethics Issues**

*Is death by neurological criteria, death?*
Legally, death by neurological criteria is death. The US UDDA, enacted in 1981, defines death as either the irreversible cessation of circulatory and
respiratory functions, or the irreversible cessation of all functions of the entire brain. While the legal standard has remained constant for 35 years, it is important to note that there continues to be a lack of consensus among academics and bioethicists. In 2008, the white paper by the President’s Council on Bioethics titled “Controversies in the Determination of Death,” concluded in two of the eighteen council members dissenting from the majority view. President’s Council members Gomez-Lobo and Pellegrino both concluded that total brain failure was not equivalent to death and thus heart-beating organ procurement is impermissible as it violates the dead-donor rule (President’s Council of Bioethics, 2008).

Others critical of death by neurological criteria have argued that those who meet the criteria for brain death do not have irreversible cessation of all functions of the entire brain, because some of the brain stem’s homeostatic functions persist. These functions include temperature and water control, and electrolyte balance (Truog & Robinson, 2003). Others contend that only functions that are significant in maintaining survival should be considered, as even with continued life sustaining treatments, patients will inevitably over hours or days, transition to cardiac arrest (Bernat, 1999).

**Death by Neurologic Criteria and Public Perception**

In regard to public perception and understanding, a survey of adults done by the Kennedy Institute of Ethics in 2004, found that two thirds of people incorrectly believe that someone who is brain dead is not legally dead. Additionally, more than half believe that a comatose patient is brain dead (Siminoff, Burant & Youngner, 2004). These perceptions exemplify the controversy about the determination of death and consequently organ donation.

Another survey of US adults after being presented a hypothetical scenario demonstrated that 71% of participants agreed that lethal organ removal should be legally permitted, and 67% agreed that they would want to donate organs if they were in an irreversible coma but biologically alive. Most, but not all, participants who were willing to donate organs “after death” were also willing to donate in irreversible coma with organ retrieval causing death (Nair-Collins, Green & Sutin, 2014). Dr. Michael Nair-Collins (2015) an academic philosopher and bioethicist argues that this public perception supports organ procurement in situations that violate the dead donor rule, casting doubt on the assertion that the dead donor rule is necessary to preserve trust and organ donation rates in the US.

**Withdrawal of support and organ procurement, cause of death?**

Currently physicians legally allow death through the withdrawal of life-sustaining treatment. This act stems from the principles of informed consent and informed refusal, which were legally supported from the New Jersey Supreme Court’s decision in the Karen Ann Quinlan case in 1976. It is also a generally accepted ethical standard that withdrawal of life support does not cause the patient’s death; rather, withdrawing life support allows the patient to die (Luce & Alpers, 2000).

Lethal organ procurement is legal, when it is tied to a valid decision to withdraw life-sustaining treatment and with consent for organ donation. In this case, donation occurs after cardiac death. The procurement of organs after removal of life support is an accepted means of organ retrieval that usually occurs in the setting of sudden illness but has also been described in individuals with progressive illness, like Amyotrophic Lateral Sclerosis (Smith, Vota, Patel & Ford, 2012). In this situation, the patient is brought to the operating room, life support is withdrawn, and when the heart stops, the physician observes the patient for a few minutes to ensure that the heart does not start beating again spontaneously. If there continues to be no circulation for 2–5 minutes, the physician pronounces the patient dead. At this point, most commonly the kidneys and liver are procured, from the now dead patient. The Institute of Medicine recommends 5 minutes of observation from the time of asystole for determination of death (Potts & Herdman, 1997). The Society of Critical Care Medicine and National Conference on Donation
After Cardiac Death report recommend that not less than two minutes is acceptable and not more than five minutes is recommended (Truog, et al., 2001; Bernat, et al., 2006).

In regard to cardiopulmonary death, the UDDA requires irreversible cessation of circulatory and respiratory functions. Under these circumstances, bioethicist, Dr. Robert Sade contends that the heart has not irreversibly arrested, as cardiopulmonary resuscitation can restore cardiac function. As the circulatory and respiratory functions are theoretically reversible, he argues that both the UDDA and the dead-donor rule are violated (Peer & Rakich, 1999).

In cases where withdrawal of life sustaining treatments is coupled with consent for organ donation after cardiac arrest, this patient or legal surrogate request may exacerbate a sense of collusion as if organ procurement is the reason for the withdrawal of life sustaining measures. Dr. Mark Aulisio and colleagues reasoned that providers and organizations should take care to ensure that the decision to withdraw life sustaining measures is made separately from and if possible, before any decision to donate organs. To safeguard against such confusion, the withdrawal of life sustaining measures should be independently warranted in light of patient values, diagnosis, and prognosis. Some organizations have required that organ donation discussion not be initiated by or pursued by health professionals with patients or surrogates until after the patient has been deemed a suitable candidate for withdrawal of life sustaining measures and made comfort care (Aulisio, DeVita & Luebke, 2007).

Advancements in organ transplantation have led to increasing demand and given the intricate relationship between transplantation and death, healthcare organizations have a responsibility to strive for best ethical practice when patients and families are most vulnerable. Organizations should align institutional mission and policies with ethical principles especially with matters surrounding acute illness and death. The lack of public understanding of neurologic injury, irreversible coma, and brain death exemplifies the need for patient and family information and support. Organizations should openly educate and counsel patients and families on death by neurological criteria. The foundation of fostering patient and family understanding about neurologic injury and coma in conjunction with prognostication should be solidified before discussions of decision to withdraw life-sustaining support. OHSU has an opportunity to improve its organ and tissue donation policies by including language and leadership example that providers should take care to ensure that the decision to withdraw life sustaining measures is made separately from and if possible, before any decision to donate organs. With this inclusion, OHSU is better poised to ethically serve patients and families at a time where they are most vulnerable.

Improving OHSU Organizational Ethics
At OHSU, there is a clear policy defining death by neurologic criteria in accordance to standard of practice as defined by professional medical association guidelines and state law. While there continues to be a lack of consensus among academics and bioethicists regarding the ethics of death by neurologic criteria, there is a strict and uniform legal standard in the US. Organizations like OHSU have a duty to follow the law, understanding that the law and ethics are two distinct entities. Peer and Rakich (1999) highlight the importance of both the law and ethics in ethical decision-making in healthcare management. They acknowledge that the law is standardized, bureaucratic, and impersonal where as ethics, is humanistic, personal, and guided by conscience.

References


