

Critical appraisals and cultural acceptance of the dead donor rule: A revisit of the contemporary transplantation era

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ABSTRACT

Transplantation remains one of the most rapidly expanding surgical specialties. Harvesting organs plays a crucial step in this highly complex surgical and communication process, and the moment at which vital organs can be donated depends on the declaration of end-of-life. This declaration must be performed by medical practitioners on the basis of clear standardized criteria of death confirmation, within competent local and regional jurisdictions, and with the use of confirmatory tests as indicated to ascertain the irreversibility of end-of-life.

The current medically and legally accepted definition of death in most societies challenges the traditional and societal understandings of the process of end-of-life. Significant criticisms and cultural oppositions to transplantation still exist, and there is an ongoing debate about the role and the status of transplantation as surgical and medical sciences continue to evolve.

By discussing the social acceptance and common understanding of end-of-life determination, we aim to highlight the current knowledge on transplant ethics with respect to the balance between the need to protect the potential organ donor and the need to donate organs at their utmost viability. No report has been done on social acceptance of transplantation in Rwanda or other Low- and Middle-Income countries (LMIC); though, as emphasis on organ transplantation evolves, we also aim to highlight the need for clear directions towards new transplantation regulations. Technical and non-technical critical arguments and moral acceptance are juxtaposed with the elucidated ethical and deontological principles to support the contemporary concept of the dead donor rule.

Key words (MeSH): Transplantation; Critical appraisal; Cultural acceptance; Brain death; Dead donor rule

INTRODUCTION

The definition of death, conceptually, is the moment of irreversible cessation of the integrative unity of a living organism [1]–[4]. Although expressed clinically as a single phenomenon [5]; physiologically it is the gradual process culminating in the somatic disassociation from the whole body, and the irreversible cessation of all vital and biological functions including but not limited to circulation, respiration, and consciousness [6], [7].

In 1959, the concept of irreversible coma was used for the first time on patients who had terminal and irreversible neurological injury with a deep unconscious status resulting in ventilator dependency [2]. Neuroscientists then started demonstrating the

process of end-of-life through neurological criteria with multiple hypotheses of brain damage and herein wanted to support the only known and legal definition of death. In 1968, the Harvard Ad Hoc Committee subsequently redefined irreversible coma as "brain death", and thereby equated "brain death" with "human death" through the newly adopted brain death criteria [5], [7]. However, despite scientific innovations at that time, the concept of death remained poorly understood by lacking a common medical and legal explanation from bioethical, scientific and religious stakeholders [8], [9].

In 1976, the proposed United Kingdom (UK) Guidelines on brain death [10]; and in 1981, when new recommendations of

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confirmatory tests for brain death at the cellular level were established, the concept of brain death was medically and legally validated as the equivalent of human death [11]. Nevertheless, in some sideline debates, a nebulous area surrounding the difference between “mostly dead” and “all dead” has led to ongoing controversies in developed countries where much progress towards resolution has been made [12]. These understandings remain largely unexplored in most developing countries, especially in places where the concept of death is socially perceived as sacred, and at times can neither be culturally nor publicly debated [13]. “Mostly dead” may be used to refer to the patient with advanced and irreversible neurological brainstem damage with no hope for a meaningful recovery [2], [4]; and “all dead” may be used to refer to the classic presentation of a patient with irreversible vital organs failure including circulation, respiration and consciousness, and after the patient has been declared dead [2], [4], [5], [13].

By 2012, the concept of death determination gained more widespread input to consistently and definitively define the end-of-life. It is now widely accepted that human death is anatomically located to the brain (with damage including the entire brainstem); and is recognized to be the irreversible loss of the capacity to breathe combined with the irreversible loss of the capacity for consciousness [14]. Three criteria are suggested to clinically confirm human death. They include somatic signs that manifest long after vital organs have ceased to function and are therefore visible on external inspection of the corpse (e.g. rigor mortis), circulatory signs (after cardiorespiratory arrest) found in hospitalized patients, and neurological signs presenting in comatose patients on mechanical ventilation and usually in a critical care environment [14].

The somatic and circulatory criteria were for a long time recognized as signifying human death, but as scientific and medical advances have led to improvement of cardiorespiratory support, the neurological criteria have gained recognition. However, the standardized use of neurological criteria at the international level remains a challenge. There is insufficient evidence to confirm or refute the neurological approach for ensuring without a doubt the exact moment neurological functions cease irreversibly [14]–[16]. There are no published reports of recovery of neurological function after diagnosis of brain death using the criteria of the American Academy of Neurology, though there is only one study that prospectively derived criteria for brain death [16]. Few reports are available on critical care and management of patients in end-of-life in Africa.

The definition of death remains unclear regarding the exact moment a human body is “all” dead or when the dying body can be declared dead; and this uncertainty creates variations in medical and legal explanations on the definition of death. The American Uniform Determination of Death act emphasizes on the declaration of Death by competent physicians after irreversible signs of end-of-life have been demonstrated beyond doubt. Transplant ethics requires that removal of organs should not be harmful to the donor, and should be beneficial to the recipient. Thus, the dead donor rule states that: “patients must be declared dead before the removal of any vital organ for transplantation” [5][17]; and herein this statement helps to

solve the totality of ethical issues surrounding the removal of organs.

In the context of a clear worldwide commitment to the principle of non-maleficence, this is an appropriate time to reflect on the difference between “mostly dead” and “all dead” with an emphasis on the latest medical, bioethical and deontological knowledge on the concept of end-of-life. There is need of an international standardized and common understanding of end-of-life. Human death can be considered in terms of medical, legal, ethical, philosophical, societal, cultural and religious perspectives [9]. The scarce evidence for harmonization of end-of-life definitions reflects the possibility that patients declared dead in one jurisdiction might still be considered alive in another. Therefore, the divergence of regulations and practices with respect to the declaration of death after clinically ascertaining the irreversibility of vital organ functions challenges the unanimous acceptance of one definition of death determination, a prerequisite to the transplantation of vital organs.

The purpose of this article is to revisit the current debate on the social (societal) acceptability and cultural understanding of the critical care of patients at the end of their life; within the framework of organ transplantation. However, as we deliver potential suggestions, a universal understanding undoubtedly requires a long period of deliberation and creation of realistic solutions given the limited resources in some countries, or adjustment of national regulations in terms of organ transplantation protocols [13].

BRAIN DEATH Vs STATUS OF “END-OF-LIFE”

Ventilatory support and cardiopulmonary bypass are reliable enough that cardiopulmonary arrest is no longer a sufficient definition of death [6]. Instead, large scale tissue necrosis within the brain defines the conceptual and biological definition of death [5], as long as no medical treatment or management exists capable of reversing the process [6][11][18–25]. Consequently, a person is and can be declared dead when his or her brain is dead [2]–[5][10][26].

Given this definition, brain death implies that life support is futile, and no attempts at resuscitation should be undertaken for the benefit of the patient [2]–[4][10]. However, we might say that there is no definition of death, but a concept of clinical phenomena which, if irreversible, determine organs death. The process involves a series of events that lead to the inevitable and continuous cascade of end-of-life.

The American Uniform Determination of Death Act [5][27],[28] provides a broader definition of death; stating that: “An individual who has 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”. This determination of death is and must be made in accordance with accepted medical standards [27]. But unfortunately, arrest of cardiopulmonary functions is still viewed by many societies and cultures as the only real death of a human being [29].

THE DIAGNOSIS OF BRAIN DEATH

Many countries acknowledge death as the total and irreversible failure of brainstem function. There may be progressive loss of viability of brainstem functions occurring in a rostral-to-caudal direction, which from the mesencephalon to the medulla oblongata explains other interlinked clinical and physiological findings: such as deep coma, absence of spontaneous breathing, absence of gag reflex, absence of brainstem reflexes and absence of corneal reflexes [10], [11]. The search for the basic anatomical description of brainstem failure elucidates the steps for determining brain death in a critically ill patient. Once the routine systematic and systemic clinical assessment has been performed, the neurological examination to determine whether a patient is brain dead can proceed only when distractive conditions have been ruled out (e.g. locked-in syndrome, hypothermia, drug intoxication, sedation, use of blocking agents, severe electrolyte imbalance, and acid-base or endocrine disturbances [10], [11]).

The neurological assessment determines the depth of coma; however, the most controversial issue related to the determination of brain death is the presence of clinical signs that suggest some retention of brain function [30]–[34]. In such cases, the evidence of brain death would come from a consistent and persuasive clinical documentation of brain death, and a confirmation through at least one corroborative investigation such as cerebral angiography, electroencephalography, transcranial Doppler ultrasound, cerebral scintigraphy or somatosensory evoked potentials. These confirmatory tests are optional in many countries, and unavailable in others. In several European, Central and South American, and Asian countries, a confirmatory testing is required by law [5]. Some countries (e.g. Sweden) require only cerebral angiography [10]. In the United States, the choice of tests is left to the discretion of the attending physician, and herein bedside tests seem to be preferred [33].

MANAGEMENT OF BRAIN-DEATH: FATALITY OR FUTILITY

In experimental animal studies, there is evidence that brain death leads to deleterious effects on many organs functions [35]–[37]. The standard management of brain-dead patients involves continuous observation, monitoring and follow-up in a critical care unit. Only under close monitoring can treatments be administered that may be in the best interests of organ donation, such as the placement of invasive hemodynamic monitors and perfusion catheters, or administration of anticoagulants and vasodilators to preserve organ function [6]. Following the experimental evidence on brain death induction, new management options have been implemented with remarkable improvement in the preservation of organ function in brain death patients. From an ethical standpoint, it should be noted that some of these treatments (for instance vasodilators) may lead to detrimental increases in intracranial pressure hastening brain tissue damage [38].

THE CONCEPT OF THE “DEAD DONOR RULE”

Organ transplantation involves medical, technological, logistical, social, ethical and legal considerations [39]. These challenges

cannot be overcome unless a proper coordination is found among relevant stakeholders. Despite great success from a medical standpoint, the organ donation process continues to be controversial. The definition of death remains unclear regarding the exact moment a human body is “all” dead or when the dying body can be declared dead. There is wide acceptance of the American Uniform Determination of Death Act [2], [40], but this medical and legal definition of death does not resolve the totality of ethical issues surrounding the removal of organs. Therefore, a dead donor rule is needed to conceptually explain medical and ethical reasons for removal of organs from the declared dead person even though not exactly “all dead”.

The dead donor rule states that: “patients must be declared dead before the removal of any vital organ for transplantation” [5], [17]. This statement was initially ethical; but has actually become legally approved [25], [41]–[43]. The statement does not support the waiting period until the cardiac arrest occurs [12] to consider the removal of organs. Instead, it covers any transplant surgeon who starts harvesting organs while the patient is irreversibly unsalvageable and pronounced dead. Moreover, the dead donor rule supports the patient’s family once clear explanations of the patient’s conditions are received, and motives for removal of organs are explained.

The bioethical and biomedical aspects are well understood, but cultural and religious challenges remain [13], [44]–[47]. The concept of death involves a fundamental series of sociological influences. Available data suggests that the most important issue for families of patients with brain death is not whether the patient is dead at the time organs are removed. More important to families is the degree of neurological injury of the patient, and the obtainment of clear and proper consent for organ donation [5], [25]. These insights help support the process of organ donation via collaboration and consent of families deciding whether continuous vegetative management is worth more than saving other humans who are still salvageable. Families must be reassured that there is no harm or wrong-doing in retrieving vital organs while proper cardiopulmonary support is provided, and that no patient dies from vital organ donation if he/she would not otherwise die from withdrawal of life support [5].

Undoubtedly, medical and ethical challenges remain, and there is pressure to declare death in a timely manner to permit early procurement of vital organs for transplantation. The question remains unanswered as to: “How early could the moment of death be defined so as to reduce subsequent insult to organ function?” [12]. Through the three criteria for determination of death; somatic signs appear late for the organs to be considered viable for transplantation, and with the circulatory signs expressed as an irreversible cardiopulmonary arrest, the acceptable observation period remains variable that a common consensus on the irreversibility of the cardiopulmonary arrest would not accurately respect the dead donor rule before subsequent transplantation or in a timely period of use of organs for donation.

The neurological criteria of determination of death remain the most adequate tool to accurately determine the irreversibility of end-of-life by respecting the viability of organs for transplantation hence its most use in the current era of

transplantation. By declaring the patient dead through neurological criteria, utilization of the dead donor rule maximizes the chance that organs will be viable for donation.

In fact, kidneys have proven relatively resistant to the disturbed homeostasis after brain death [14], but the same could not be said for the function of the heart, lungs, and liver. Some countries, for instance the United States of America (USA), require the medical practitioners determining brain death to immediately notify transplantation organizations even before critical care measures are taken for an eventual organ donation [16].

HUMANISTIC ACCEPTANCE OF THE DEAD DONOR RULE

Scholars from diverse religions still debate the concept of brain death [8], [42], [48]–[50]. For example, Rwanda continues to have a strong catholic population and therefore the views of the Catholic Church remain very important to many members of the Rwandan population. Pope Benedict XVI stated that “vital organs can be extracted - ex cadaver (from a dead body) -, if and only if, the donor’s true death can be certified beyond doubt” [49], [51], [52] presuming that “if death criteria turn out to be wrong, then we would no longer be able to use brain-death criteria with moral certainty” [48]. Moreover, in late 1957, a problem of medical prolongation of life was also asked to Pope Pius XII. The answer was another question back to medical doctors affirming that “the criteria for timing (not defining) death under artificial life support should be left to the attending physician” [20]. Therefore, from these two eminent and influential statements it is clear how important this question is and has been over time.

It is widely believed in the religious community that the degree of certitude required to determine death has been influenced by the anticipated removal of organs for transplantation [8]. Studies show that some religious groups oppose organ donation because of fundamental beliefs that the human body is a trust that has been given and owned by God, which, should not be physically violated by removing organs for the protection and integrity of personhood [5], [13]. One religious group took even a stance in support of organ donation. The United Methodist Church (UMC) issued a statement at its regional conference in 2007 (USA) which supported transplantation after brain death. The UMC statement asserted that the moment of death is not when the heart stops beating but rather, the time when all brain waves activity has ceased [53]. The UMC statement, however, did not specify when it is permissible to remove organs, or whether it is appropriate to perform organ donation before brain death.

On the other hand, studies have shown that some people prefer not to be kept alive on life support when there is no hope for a meaningful recovery [54]. Certainly, any death in sudden circumstances is difficult to accept; and it often comes with varying degrees of denial that can delay or prevent acceptance of the diagnosis. Furthermore, potential conflicts of interest can occur between the end-of-life care of donors and the needs of potential organ recipients; and this contributes to suspicions among patient families of substandard care delivery. As organ donation is generally seen as a selfless and altruistic act and as it is frequently proposed as offering some later consolation to

grieving relatives, the motivation for declaration of death should never be that of assessment of organs functions, or the process of organ donation itself. These two actions should always be of secondary consequence to the appropriate end-of-life management of the patient; otherwise, transplant programs would suffer if such actions substantiate public fears that the needs of dying patients will be given secondary importance to medical pressure to perform transplantation.

The ethical challenge is to secure a commonly understood and clearly interpretable definition of death that could be recognized without mistake [25]. Ethical and legal principles supporting the rights of dying patients and their families to forgo burdensome medical intervention have been well established in Western countries [55]. Competent patients and/or their legally designated surrogates clearly also have the right to donate vital organs for transplantation after death [56].

The process of organ donation begins with the decision to withdraw life-sustaining medical therapy, progresses through the compassionate care of the dying patient, and ends after a patient donates their vital organs. Donation after death combines at least two ethically complex scenarios: the care of a patient at the end of life, and, the patient’s generous and selfless act to donate organs. When these two events are juxtaposed, there is a significant potential for conflict, confusion, and error. Without thoughtful planning and skilled professionals, this can lead to harmful short and long-term results for families, professionals, and the organ donation system itself.

In deontological moral reasoning, actions are intrinsically right or wrong regardless of outcome [6]. It is imperative to know that the prediction of death should not be confused with the diagnosis of death [2]–[5], [27], [28]. In line with the patient’s wish to donate their organs, the process of organ explantation, should be started as soon as the intention to continue care is deemed ineffective and worthless, and only if saving other human lives can be planned [6], [54].

THE DEAD DONOR RULE IN RWANDA

There is scarcity of information and reporting transplantation ethics in Rwanda and in many LMICs. The current cultural and societal understandings on transplantation remain assumptive with relative misconceptions of organ donation in the general population. Transplant programs, for instance the corneal and kidney transplants that are done at tertiary level hospitals have been developed and have had good outcomes [57], [58]. Many more transplants are planned in the future for the sake of a growing number of patients in need of transplantation.

The current regulations on organ donation in Rwanda lack conceptual analysis on the definition or the declaration of end-of-life, a prerequisite to the incorporation of the dead donor rule in the transplantation scheme; therefore, limiting possibilities for a complete transplantation package in the health care system. No single definition of death in proper legal or medical terms is found in any legal or administrative report. Only the conditions and the competent physicians to declare death are reported [59]. Hypothetically, death is defined as the irreversible cessation of the cardiopulmonary function.

However, with regard to the American Uniform Determination of Death, this definition is incomplete

The revisit of the contemporary transplantation era shows gaps and lack of reports on the perception of death and its definition in Rwanda and other LMICs; limiting therefore progress to the acceptance of organ donation in the general community. The single regulation on organ donation in Rwanda mentions the modalities and conditions of transplantation, but it does not highlight with accuracy the moments organs might be harvested without challenges to infringe on transplant ethics [59]. This paper calls on local and international researchers to survey on all aspects (social, ethical, and cultural) that support in addressing controversies around organ donation in our local contexts. There is an increasing need for organ transplant locally and hence, many transplant programs need to be well supported legally, medically and socially.

CONCLUSION

Arguably, living organisms preserve themselves and, for that, "must, can, and usually do engage in interaction, exchange, and commerce with the surrounding world" [3], [14], [18]. Today, if there are no signs of consciousness in addition to the absence of spontaneous breathing; a standardized clinical judgment that these physiological facts cannot be reversed, as well as the patient (in end-of-life process) having been declared dead, organ donation can be undertaken to preserve other living organisms

It remains problematic to know the moment the organ donation does not harm the donor. Researchers of all related areas have been and are still obsessively interested to find solutions towards a harmless interaction and subsequent organ donation among human beings.

Many social surveys and clinical reconsiderations on the perceptions of the modalities and benefits of organ donation are needed in Rwanda and other LMICs. Transplantation programs are evolving due to the high demand of organ donation, but current regulations do not support all necessities of transplant ethics. Knowledge and appraisals of the understanding of end-of-life process and organ donation should be reported and applied for the sake of the development of transplant programs in Rwanda.

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