

ROLE OF FORENSIC NUEROLOGISTS IN DETERMINING BRAIN DEATH

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ABSTRACT

Until few decades ago, death was thought to be a definite point in time that marked the end of life. With the availability of ventilators, defining when death has happened is getting more challenging, as cessation of life functions is not always synchronous across organ systems. Neurological determination of brain death is a difficult assessment that nonspecialists and families may misunderstand. Recent guidelines define how to do such an evaluation and are available to clinicians, with the time of death in adults and children determined by the final defining test—the apnea test. With the availability of ventilators, defining when death has happened is getting more challenging, as the termination of life functions is sometimes not synchronous across organ systems. With increased access to intensive care units (ICUs) even in cities, and the government making it essential to notify brain death to facilitate cadaveric organ transplants, neurosurgeons and neurologists must thoroughly understand the nuances of brain death. International organizations have widely condemned the ethics of commercial organ donation and transplant tourism. The legal and ethical standards that we follow universally in organ donation and transplantation are particularly crucial for the future because they can be used to resolve controversies over developing sciences such as cloning, tissue engineering, and stem cells.

The importance of early detection, the problems in the clinical diagnosis of brain death, the limitations of so-called confirmatory testing, and the moral and ethical issues will be discussed. This paper delves into the most recent guidelines and methods for detecting brain death, focusing on clinical assessments, brainstem reflex testing, and the use of supplementary tests. Further it aims to improve the competency of healthcare workers from many disciplines, encouraging an interprofessional approach to handling this difficult part of patient care. This research work also provides an insight to traverse the clinical, ethical, and legal challenges of brain death, resulting contemporary suggestions and upgradation in the existing framework. This study intends to pave the road for legislative reforms in India that control unethical practices and promote organ donation by critically assessing the current legal framework and relying on overseas experiences. This research paper delves into the multifaceted issues of organ transplantation in India, with the goal of proposing reforms to combat unethical practices and increase organ supply.

Key Words:

Apnea testing, Neurological criteria, organ transplantation, brain stem

CHAPTER I

INTRODUCTION

1.1 INTRODUCTION

Thanatology, the science dealing with the study of death, has been in existence for centuries. Legal and medical quandaries regarding the definition of death are not new. In his 'Historia Naturalis', the Roman author, Pliny the Elder, wrote that "so uncertain is men's judgment that they cannot determine, even death itself". Perceptions of death have been reflected in poetry, literature, legends and pictorial art. Most ancient civilizations accepted death as an easily determined empirical fact, not requiring further elaboration. Before 1960, death was defined as the complete and irreversible cessation of spontaneous cardiac and respiratory functions. Brain death was first described by two French physicians, Mollart and Goulon and termed 'coma depasse' (a state beyond coma). They differentiated 'coma depasse' from 'coma prolonged', the latter being the condition, which is now termed as the persistent vegetative state.

The biological death of the whole human organism cannot and is not required to be proven during the diagnosis of brain death. While there is unanimity that confirmation of absence of brain stem reflexes is fundamental to the clinical determination of brain death, there are wide variations in the requirements for the conduct of the apnea test. Most countries agree that the clinical diagnosis of brain stem death is sufficient for certification of death in adults. In spite of the existing guidelines, variations and inconsistencies necessitate the requirement for an international consensus to define when a person can be declared brain dead. The clinical evaluation criteria must be strictly adhered to and the limitations of so-called confirmatory tests recognized.

The concept and understanding of brain death were first accepted following the

Sydney Declaration in 1968⁸⁶¹, and many countries began their programmes in the early 1970s by establishing the legal foundation for brain death, followed by organ donation. The Transplantation of Human Organs Act (THOA) of 1994, as amended in 2011 and rules issued in 2014, serves as the statutory framework for brain death and organ donation in India⁸⁶². This act established a transparent and strong mechanism to support the critical cause of organ transplantation in India.

1.2 DEFINITION

1.2.1 Brain Death

The term 'brain death' sounds, perhaps, very specific and precise. But different scholars have various views regarding the definition. Sometimes 'Brain death' is considered such an ambiguous and confusing term that it ought to be abandoned⁸⁶³. The term is also important because it means same thing to doctors, lawyers, legislators, and society at large. In this regard it is useful to review briefly the criteria the medical profession uses to assess brain death and to review the various efforts made by responsible organizations to arrive at a statutory statement of the meaning of brain death. The term 'death' refers to the rapid or gradual transition from life to death.

There are four tiers of definitions for this formal concept, each of which can be subject to legislation. The concept, physiological standards, operational criteria, and specific tests or methods are all important considerations. The concept of death is inherently philosophical. Possible definitions of death at this level include "permanent cessation of integrated functioning of the organism as a whole," "departure of the animating or vital principle," or "irreversible loss of personhood." These abstract definitions provide little tangibility. While they can aid in

⁸⁶¹ Gilder, S. S. (1968). Twenty-second world medical assembly. *British Medical Journal*, 3(5616), 493.

⁸⁶² National Organ Transplant Program. Director General of Health Services India. [Last accessed on 2017 Nov 21]. Available from: <http://www.dghs.gov.in>.

⁸⁶³ Veatch, *Defining Death: The Role of Brain Function*, 242 J.A.M.A. 2001, 2002 (1979).

determining a person's death, they may also impact the development of standards and criteria. In establishing the broad physiological standard for recognizing death, the definition becomes more medicotechnical, but not entirely so. Defining death based on organ systems, physiological functions, or human activities raises philosophical concerns. The definition of physiological norms is further clarified by operational criteria. "Cessation of spontaneous circulatory functions," while the Harvard Committee has suggested criteria for "cessation of spontaneous brain functions" that include severe coma, lack of reflexes, and absence of spontaneous respiratory and muscular movements. There are particular methods and tests to determine whether the requirements are met. Among the particular measures of cardiac contraction and blood flow are the pulse, heartbeat, blood pressure, ECG, and assessment of blood flow in the retinal arteries. Specific tests of the "brain function" requirements listed above include the pupils' appearance and responsiveness to light, their reaction to painful stimuli, and the monitoring of their movement and respiration over a certain amount of time.

Harvard Medical School's Ad Hoc Committee defined brain death in 1968. The committee was chaired by Dr. Henry K. Beecher. The Harvard Committee described in considerable detail three criteria of 'irreversible coma':⁸⁶⁴

- 1) unreceptivity and non-responsivity to externally applied stimuli and inner need
- 2) absence of spontaneous muscular movements or spontaneous respiration
- 3) no elicitable reflexes

The Uniform Determination of Death Act (UDDA) of 1980 proposed a legal definition of death, which has since been widely accepted. The act reads: "An individual who has sustained either irreversible cessation of circulatory and

respiratory functions, or irreversible cessation of all functions of the entire brain, including the brain stem, is dead." Death, therefore, is a result of either a cardiopulmonary arrest with irreversible cessation of respiration and circulation, or it is a result of irreversible loss of all functions of the brain, including the brain stem. The latter is defined as Brain Death. A patient determined to be brain dead is clinically and legally dead.

1.3 REVIEW OF LITERTURE

Ganapathy, K. Brain death revisited. Neurology India:⁸⁶⁵

This article gives a detailed overview on the entire concept of brain death. It specifies the tests that are being used to determine brain death. The article highlights the neurological criteria for determining brain death. It also gives a clear view on the Indian perspective. The report gives a conclusive idea on determination of brain death and its legal implications. It also brings in the ethical aspects into its ambit. The technologies and methods followed in India for evaluation of brain death were also sufficiently emphasized.

Burkle CM, Sharp RR, Wijdicks EF. Why brain death is considered death and why there should be no confusion.⁸⁶⁶

The legal implication and the judicial disputes involved in determination of brain death is discussed. The disputes do not involve the challenges in India. But it sheds light on the medical negligence of the medical professionals and the ethical and moral issues associated with determination of brain death.

Organ Transplant Law: Assessing Compatibility with the Right to Health:⁸⁶⁷

This report has systematically highlighted the indicators to identify changes needed in the

⁸⁶⁴ Ben Sarbey, *Definitions of Death: Brain Death and What Matters in a Person*, 3 J Law Biosci 743 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5570697/>.

⁸⁶⁵ 66(2):p 308-315, Mar-Apr 2018. | DOI: 10.4103/0028-3886.227287

⁸⁶⁶ Neurology. 2014 Oct 14;83(16):1464-9. doi: 10.1212/WNL.0000000000000883. Epub 2014 Sep 12. PMID: 25217058; PMCID: PMC4206160.

⁸⁶⁷ Organ Transplant Law: Assessing Compatibility with the Right to Health (Vidhi Legal, 2017) < <https://vidhilegalpolicy.in/research/organ-transplant-law-assessing-compatibility-with-the-right-to-health/>>

Indian organ Transplant to make it compatible with the international human right to health. This report has critically analysed the Transplantation of Human Organs and Tissues Act, 1994, in the light of its objectives and the above indicators. This report is also very comprehensive in terms of its recommendations.

Dr Anju Vali Tikoo, 'Transplantation of Human Organs'⁸⁶⁸

This article is very comprehensive and deals with the Indian legal scenario. This article points out the various lacunas in the Indian laws about organ transplantation, like the issues of consent, autonomy of the deceased, public policy issues, problems with organ donation and retrieval, etc. The author has also suggested the changes that could be made to these laws. However, this article has yet to discuss international practices about organ transplantation.

1.4 OBJECTIVES

- 1) To comprehend, comparatively analyse and assess the international practices about organ transplantation.
- 2) To identify, examine and analyse the various issues and challenges about organ Transplantation in India.
- 3) To examine and recommend ways to regulate unethical practices about organ transplantation and promote the supply of organs in India.
- 4) To evaluate and critically analyse legal framework and judicial decisions about organ Transplantation in India.
- 5) To discuss the modes of determination of brain death including the neurological criteria
- 6) To examine the procedures and the medico legal implications of brain death

- 7) To analyse the legal dispute and judicial approach to determination of brain death and organ donation

1.5 RESEARCH QUESTIONS

- 1) What are the ethical and legal implications in determining brain death?
- 2) What are the existing legal frameworks in India to determine brain death?
- 3) What are the various issues and challenges concerning organ transplantation in India?
- 4) How does the Indian legal regime deal with organ transplantation?
- 5) How do other legal jurisdictions regulate organ transplantation?

1.6 RESEARCH PROBLEM

Brain death is constituted as a specific issue in determining the death of a person. Declaration of brain death has a bearing on moral and ethical perspectives of a person. A major part of the brain death determination and declaration involves neurological criteria and the report of the neurologist after adhering to the established tests and procedures. The tests and procedures along with the reporting of brain death is itself a question of dispute in other countries, where its validity is being questioned and the doctors are legally prosecuted for their duty. While in India procedure for determining brain death is not given sufficient emphasis due to the existence of a surplus organ need. Neurologist determining brain death create awareness and focus on organ donation rather than making a challenge in the medical procedure. The definition of brain death is itself found in the organ donation Act in India. In the Indian context the lack of conclusive and comprehensive laws that define brain death and the specifications as to the procedure is a loop hole to circumvent the determination of brain death. Although there is a need for organ donation the right of the dead and the associated persons should not be neglected.

⁸⁶⁸ Dr Anju Vali Tikoo, 'Transplantation of Human Organs: The Indian Scenario' [2017] 1 ILJ Law Review 147

Thus, the paper looks into the existing legal framework and the lacunas in brain death determination and associated organ donation.

1.7 RESEARCH METHODOLOGY

The approach employed for this paper is doctrinal, relying on secondary sources of literature with a descriptive and analytical research design. Initially, the paper will offer a descriptive introduction to the topic, followed by an exploration of issues and challenges in organ transplantation and the regulatory framework in India, drawing from legislation and judicial decisions. Subsequently, it will adopt an analytical stance, comparing the Indian framework with those of other jurisdictions and international bodies. Upon identifying and examining policy gaps, the researcher will conclude by suggesting reforms for an improved legal framework.

CHAPTER II

EVOLUTION AND DEVELOPMENT OF THE CONCEPT OF BRAIN DEATH

2.1 BACKGROUND OF THE STUDY

The common law standard defines death as “a total stoppage of the circulation of the blood, with a cessation of the animal’s vital activities, such as respiration, pulsation, etc.” Many doctors believe traditional vital indicators are unreliable for unconscious hospitalized patients on medications, mechanical ventilators, or cardiac pacemakers. After the Harvard Committee’s recommendations on determination of death questions arose in regard to artificial support provided to patients who cannot perform vital functions. Further organ transplantation and regaining the function of that organ also lead to ambiguity. In certain cases the determination of death by the neurologist was put to question depending on the conventional definition of death as specified in the Black’s Law Dictionary. Further questions arose as to whether neurological definition of death can be adhered to or traditional circulatory regulations should also be imbibed in order to determine death. Courts and

medical professionals may no longer presume that figuring out if and when someone has passed away is usually an easy task. In certain cases, it has become more challenging due to the development and application of advanced gear to artificially sustain both respiration and circulation. When a cardiac pacemaker or mechanical respirator is used, the importance of the conventional “vital signs” heartbeat, pulse, and respiratory movements as markers of ongoing life is called into question. The standing of the beating heart as one of the most trustworthy if not the most trustworthy signs that a person is still alive has also been weakened by the capacity of an organ recipient to continue living after having his own heart replaced by another’s. Four decades ago, law and medicine clashed over death.

Before the advent of support systems, death was assumed to have taken place when the heart irreversibly stopped. Transplantation programs with the need for viable organs necessitated re-evaluation of the concept of death. Today, brain death is considered equivalent to death of the individual, and death of the brain stem is accepted as death of the brain. Prior to availability of mechanical ventilation, patients without a respiratory drive would become anoxic and die. Today patients with severe, irreversible and nearly total brain dysfunction, can be maintained on a ventilator nearly indefinitely.⁸⁶⁹

2.2 ROAD TO UNIFORM BRAIN DEATH LEGISLATION: HISTORY OF INCONSISTENT BRAIN DEATH LAWS

In the 1970s, states took on the problem of enshrining medical consensus on the use of neurological criteria to determine death through legislation. Unfortunately, there was no unified legal formulation, and many alternatives were used. For example, Kansas passed the first brain death statute in 1970, and numerous other states followed suit⁸⁷⁰. However, the Kansas

⁸⁶⁹ Ganapathy, K. Brain death revisited. *Neurology India* 66(2):p 308-315, Mar–Apr 2018. | DOI: 10.4103/0028-3886.227287

⁸⁷⁰ P.J. O’Hara, “Medical-Legal Agreement on Brain Death: An Assessment of the Uniform Determination of Death Act,” *Journal of Contemporary Law* 8

model was flawed since it proposed two sorts of death rather than two methods for determining a single phenomenon of death⁸⁷¹. Over the next decade, the ABA, the AMA, and the National Conference of Commissioners on Uniform State Laws each submitted model statutes, but none of them were widely adopted⁸⁷².

Adding to the cacophony of statutory approaches, states did not consistently use any of the various models. First, some versions omitted to mention the brainstem, implying that there was no distinction between permanent unconsciousness caused by loss of higher brain function and death⁸⁷³. Additionally, some versions did not include the typical cardiopulmonary criterion for death, leading to confusion about their status⁸⁷⁴. Third, some versions mentioned organ donation, implying that determining death using neurological criteria was only relevant to donors and was solely driven by organ donation⁸⁷⁵. Fourth, some versions emphasized the continuance of organ support after brain death, implying that brain death is not the same as human death⁸⁷⁶. Finally, several versions are proposed using different criteria to declare death for various purposes (e.g., inheritance, taxes, criminal trials, and medical treatment)⁸⁷⁷. To be clear, there was no debate over the fundamental concept of brain death. Most states regarded brain death as death, but the variety of statutory models proved confounding. Differences in statutory terminology led to the possibility that a person could be both living and dead in different states⁸⁷⁸.

2.3 THE UNIFORM DETERMINATION OF DEATH ACT:

By 1979 the ABA, the AMA, and the National Conference had each independently adopted so-called model statutes. Nevertheless, the trend was away from uniformity as the various states opted to enact different model statutes. As a result of the proliferation of brain death statutes, the definition of brain death seemed to be in dispute and worse, seemed to vary from profession to profession. To rectify the confusion, representatives from the ABA, the AMA, and the National Conference convened for the purpose of drafting a model brain death statute agreeable to all three organizations⁸⁷⁹. In fact, the three groups had no disagreement over substance. As Mr. Horan explained, "Each of the three organization's definitions required irreversible cessation of all brain function which can be determined in accordance with reasonable medical standards". Consequently, the representatives were able to reach a compromise, which was the Uniform Determination of Death Act. By 1981, all three organizations had ratified the new Act, thereby ending even the appearance of any disagreement about the proper definitional statement of brain death⁸⁸⁰. The Uniform Determination of Death Act, which already has been adopted by Mississippi, provides as under: "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 brain stem, is dead."
- The determination of death must be made in accordance with accepted medical standards. The first part of the Act is a codification of the common law standard and the second part of the Act is a codification of the brain death standard.

(1982): 97-122, note 22 (including Maryland, New Mexico, Oklahoma, and Virginia).

⁸⁷¹ F.J. Veith, "Brain Death: I. A Status Report of Medical and Ethical Considerations," *JAMA* 238 (1977): 1651-1655.

⁸⁷² President's Commission, *supra* note 17, at 62-68.

⁸⁷³ B. Nipper, "Legislating Death: A Review and Proposed Refinement of the Uniform Determination of Death Act," *Houston Journal of Health Law & Policy* 17 (2017): 429-462, at 442.

⁸⁷⁴ Ryan, *supra* note 13, at notes 100, 106-107.

⁸⁷⁵ *Id.*, at note 58.

⁸⁷⁶ *Id.*, at note 58.

⁸⁷⁷ Calling the same person "dead" for one purpose but "alive" for another would engender nothing but confusion. Therefore, we need a precise time of death, "a single set of standards ...appropriate for all legal purposes." President's Commission at 10, 60; Ryan, *supra* note 13, at note 50; O'Hara, *supra* note 20, at notes 92-96.

⁸⁷⁸ UDDA, *supra* note 6, at prefatory note.

⁸⁷⁹ Horan, *supra* note 31, at 25.

⁸⁸⁰ A.B.A.: *The Voice of the Profession-Annual Report 1980-1981*, 67 A.B.A.J. 1479 (at 12 of Annual Report) (1981) ("This is an attempt by the three organizations to achieve a uniform public policy and to reduce confusion and uncertainty in this crucial medical-legal area.")

CHAPTER III

INTERNATIONAL LEGISLATIONS REGARDING BRAIN DEATH

3.1 THE KANSAS BRAIN DEATH STATUTE:

As noted at the outset, Kansas was the first state to enact a brain death statute in any form. Kansas legislation, written in response to advances in organ transplantation and medical support for dying patients, offers alternative definitions of death, presented in two paragraphs.

- 1) According to the first definition, a person is declared "medically and legally dead" if a physician concludes there is no spontaneous respiratory or cardiac function and resuscitation efforts are unsuccessful.
- 2) According to the second "definition," death occurs when there is no spontaneous brain function after reasonable measures to preserve or restore spontaneous circulatory or respiratory function fail.

That is, a patient may be declared dead by a doctor applying either the common law criteria or the brain death criteria. As per the statute "Death is to be pronounced before artificial means of supporting respiratory and circulatory function are terminated and before any vital organ is removed for the purpose of transplantation." Other states have enacted brain death statutes patterned exactly or closely after the Kansas model⁸⁸¹, for instance the Maryland statute. The 2019 statute of determination of death reads as:⁸⁸²

Determination of death: 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 brain stem, is dead.

A determination of death must be made in accordance with accepted medical standards.

Criticism of the Kansas Statute regarding determination of death:

- 1) It creates a dichotomy regarding the criteria of determination of death.
- 2) It creates uncertainty among the medical practitioners as to the treatment and time period of resuscitation.
- 3) It also leads to an ambiguity in organ transplantation and organ donation from the person determined to be dead.

3.2 THE CAPRON-KASS BRAIN DEATH STATUTE:

In an influential 1972 law review article, Professor Capron and Dr. Kass analyzed the Kansas statute and found it lacking⁸⁸³. In their words, "The primary fault with this legislation is that it appears to be based on, or at least give voice to, the misconception that there are two separate phenomena of death". Capron and Kass suggested as an alternative to the Kansas statute, a statute that they drafted. In order to reflect the concept of death as a single phenomenon, Capron and Kass provided in their statute that death could be assessed using the brain death criteria only under circumstances where artificial means of support preclude a determination that spontaneous respiratory and circulatory functions have ceased. The brain death standard in the Capron-Kass proposal states that irreversible cessation of spontaneous brain functions is supplemented with the inherently ambiguous statement that, "Death will have occurred at the time when the relevant functions ceased." In spite of the ambiguity in the word 'relevant', several states have enacted Capron-Kass type statutes⁸⁸⁴. Capron and Kass

⁸⁸¹ See, e.g., MD. ANN. CODE art. 43, § 54F (1980); N.M. STAT. ANN. § 12-2-4 (1978).

⁸⁸² 77-205, 2019 Kansas statute, *Statute | Kansas State Legislature*, https://www.kslegislature.gov/li_2020/b2019_20/statute/077_000_0000_chapter/077_002_0000_article/077_002_0005_section/077_002_0005_k/#~:text=77%2D205,the%20brain%20stem%2C%20is%20dead. (last visited Jun. 9, 2025).

⁸⁸³ Capron & Kass, *A Statutory Definition of the Standards for Determining Human Death: An Appraisal and a Proposal*, 121 U. PENN. L. REV. 87 (1972).

⁸⁸⁴ See, e.g., ALA. STAT. § 09.65.120 (Supp. 1981); IOWA CODE ANN. § 702.8 (West 1979).

model which differentiates four levels at which death may be “defined”:

- 1) the basic,
- 2) general physiological standards,
- 3) operational criteria
- 4) specific tests and procedures

3.3 THE AMERICAN BAR ASSOCIATION'S MODEL DEFINITION OF DEATH ACT

In 1975, upon the recommendation of the Law and Medicine Committee, the ABA's House of Delegates voted to endorse the text of a Model Definition of Death Act⁸⁸⁵. The Act provided: “For all legal purposes, a human body with irreversible cessation of total brain function, according to the usual and customary standards of medical practice, shall be considered dead.” Dennis J. Horan, a former chairperson of the Law and Medicine Committee, has written that the ABA's 1975 Act differs from the Kansas and Capron-Kass models in that there is no explicit provision made for determination of death based on the heart and lungs standard, although such is implied. Thus, whereas the common law standard contains an implicit recognition of the brain death standard⁸⁸⁶, the ABA's 1975 Model brain death act contains an implicit recognition of the common law standard. A number of states, including California, have enacted brain death statutes patterned after the ABA's 1975 Act⁸⁸⁷.

3.4 THE NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE

Law's Uniform Brain Death Act In 1978 the National Conference approved a Uniform Brain Death Act⁸⁸⁸. The 1978 Uniform Act provides: “For legal and medical purposes, an individual who has sustained irreversible cessation of all functioning of the brain, including the brain stem, is dead.” A determination under this

section must be made in accord with reasonable medical standards. At least one state has adopted the Uniform Brain Death Act as written, and three others have based statutes on it.

3.5 THE AMERICAN MEDICAL ASSOCIATION'S MODEL DETERMINATION OF DEATH STATUTE

For several years the AMA opposed a legislative brain death standard. Because of the rapid advances common to medicine, the AMA feared that a statute would be too inflexible. By 1977, however, the AMA's House of Delegates went on record as stating that, Permanent and irreversible cessation of the brain constitutes one of the various criteria which can be used in the medical diagnosis of death. In 1978, the House of Delegates voted to approve a Model Determination of Death Act which stated:

“A physician, in the exercise of his professional judgment, may declare an individual dead in accordance with accepted medical standards⁸⁸⁹.” Such declaration may be based solely on an irreversible cessation of brain function. That Act was amended, however, at the 1979 Interim Meeting of the House to provide that, an individual who has sustained irreversible cessation of circulatory and respiratory functions or irreversible cessation of functioning of the entire brain is to be considered dead and that determination of death by a physician is to be made only in accordance with accepted medical standards⁸⁹⁰. Apparently, the AMA set aside its reluctance to codify a brain death standard once it became clear to the AMA that it was possible to support a statutory form that would not legislate specific neurological criteria for pronouncing death.

⁸⁸⁵ *House Adopts Legal Definition of Death*, 61 A.B.A.J. 463, 464 (1975).

⁸⁸⁶ See *supra* text accompanying notes 8-11, for a discussion of the implicit recognition of brain death by the common law standard.

⁸⁸⁷ See, e.g., CAL. HEALTH & SAFETY CODE § 7180 (West Supp. 1981); IDAHO CODE § 54-1819 (1981).

⁸⁸⁸ 12 UNIFORM LAWS ANN. 15 (Supp. 1982).

⁸⁸⁹ M.I.S.S. CODE ANN. § 41-36-1 & -3 (1981). As explained in note 3 and accompanying text, *supra*, Indiana and Washington have judicially adopted the Uniform Determination of Death Act.

⁸⁹⁰ 12 UNIFORM LAWS ANN. 208, 209 (Supp. 1982).

CHAPTER IV

CAUSES OF BRAIN DEATH

4.1 CAUSES LEADING TO BRAIN DEATH

Extracranial or intracranial incidents can also cause brain damage that led to death. Intracranial causes are then classified as global versus localized, and ischemic versus hemorrhagic. The primary extracranial event that causes brain death is a cardiac arrest followed by a delayed or inadequate cardiopulmonary resuscitation, which results in protracted and severe reduction of blood supply to the brain. Hypoxia and ischemia disrupt cellular osmoregulation, resulting in increased water entry into the brain parenchyma and brain edema. Because the brain is surrounded by a stiff skull, this swelling will eventually disrupt blood flow and produce further hypoxia, culminating in further edema. The negative consequence of this ongoing brain edema is an increase in intracranial pressure, which, if sufficiently high, compresses the entire brain and the brain stem, causing herniation or complete cessation of cerebral circulation, resulting in aseptic necrosis of brain tissue and, as a result, no blood uptake⁸⁹¹. Traumatic brain injury and subarachnoid hemorrhage are the most prevalent intracranial causes of brain death in adults, whereas abuse is said to be more common in children than motor vehicle accidents or suffocation. The common mechanism of brain injury is an increase in intracranial pressure over the mean artery pressure⁸⁹², which causes a suspension of cerebral blood flow and persistent cytotoxic injury to the intracranial neuronal tissue, as previously reported⁸⁹³. The United Kingdom Medical Royal Colleges' criteria for the diagnosis of brain death include a list of preconditions that must be met before official tests for the absence of brain stem function may be done⁸⁹⁴.

These preconditions require the identification of a clear cause of irreversible brain damage, as well as a set of necessary exclusions that specifically exclude reversible causes of brain stem depression such as depressant drugs, neuromuscular blocking agents, hypothermia, and metabolic imbalance. Clinicians must also be mindful of the risks of brain death misinterpretation in patients with illnesses that may resemble brain stem death. The most common conditions on that list are locked-in syndrome and acute severe inflammatory polyneuropathies that can present as locked-in syndrome, hypothermia, and drug intoxications⁸⁹⁵.

The essential neurological premise that the brainstem is the last structure to lose function has been known for centuries, including by Jean-Martin Charcot, one of the founders of neurology, who stated that it is the last structure to die. When brainstem function is gone, breathing is the first to stop, followed by the heart. This agonal sequence may be avoided if the patient is intubated, placed on a mechanical ventilator, adequately oxygenated, fluid resuscitated, and vasopressors and vasopressin are administered during the acute period. Once an untreatable catastrophic brain structural injury has been demonstrated while in this supported state, there is no recovery and no known successful medicinal or surgical intervention.⁸⁹⁶ Absence of motor responses, loss of all brainstem reflexes, and apnea all indicate irreversible conditions. After reaching this point, blood pressure becomes unstable and frequently falls despite attempts to regulate it. Cardiac arrhythmias develop, and multisystem damage is common as a result of a widespread inflammatory response and intravascular coagulation. Support methods are difficult and frequently fail, and maintaining a brain-dead body is nearly impossible. There is

⁸⁹¹ Machado C. Diagnosis of brain death. *Neuro Int.* 2010;2(1):e2.

⁸⁹² Wijdicks EF. Determining brain death in adults. *Neurology.* 1995;45(5):1003-1011.

⁸⁹³ Ashwal S, Schneider S. Brain death in children. *Pediatr Neurol.* 1987;3(1):5-11.

⁸⁹⁴ Conference of Medical Royal Colleges and their Faculties in the UK. Diagnosis of brain death. *Br Med J.* 1979;1(6159):322.

⁸⁹⁵ Plum F, Posner JB. *The Diagnosis of Stupor and Coma.* Philadelphia: Davis; 1966.

⁸⁹⁶ Christopher M. Burkle, Richard R. Sharp & Eelco F. Wijdicks, *Why Brain Death Is Considered Death and Why There Should Be No Confusion*, 83 *Neurology* 1464 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4206160/>

no question that brain death is a distinct clinical neurological state that differs from all other forms of acute or extended coma. Brain death, according to the medical judgment of practicing neurointensivists, neurosurgeons, and all neurological and neurosurgical associations and academies around the world, constitutes person death.

4.2 BRAIN DEATH IN CHILDREN

Trauma, anoxic encephalopathy, infections, and cerebral neoplasms are the most common causes of brain death among children. Although the criteria of brain death and the declaration process in children are quite similar to those in adults, the American Academy of Pediatrics issued some specific guidelines in 2011 that are listed below⁸⁹⁷. Brain death cannot be diagnosed in premature neonates under 37 weeks gestational age. Two examinations, one of which includes apnea testing, must be completed, each separated by an observation period. Examinations should be completed by multiple attending physicians⁸⁹⁸. Apnea tests may be done by the same doctor. The suggested observation period is 24 hours for term neonates (37 weeks gestational age) to 30 days of age, and 12 hours for infants and children (>30 days to 18 years). Neonatal and baby assessments should be completed by pediatric specialists with critical care training. The initial evaluation establishes whether the youngster meets the established neurological examination criteria for brain death. The second examination confirmed brain death due to an unchanging and irreversible state. If there are questions or inconsistencies in the assessment, neurological function should be assessed 24 hours or longer after cardiopulmonary resuscitation or other serious acute brain trauma⁸⁹⁹. In addition, age-related observation periods and specialized neurodiagnostic testing were advised for children under the age of one

year. For children older than one year, the task group ruled that brain death could be diagnosed primarily clinically, with laboratory tests optional. When auxiliary studies are used, a second clinical examination and apnea test should be done, and any completed components must be consistent with brain death. In this case, the observation period may be reduced, and the second neurological examination and apnea test (or any other components that can be done safely) can be performed at any time thereafter. Given the scarcity of evidence, these rules are heavily reliant on consensus opinion⁹⁰⁰. As a result, they have generated some controversy. Some feel that brain death cannot be properly diagnosed in very young infants. Several countries' committees opted to proclaim brain death in youngsters as young as two months old. In 2006, a Canadian panel issued recommendations with slightly different conditions for children's brain death criterion. Full-term babies over 48 hours and under 30 days old require serial determinations spaced by 24 hours. Clinical criteria should also include the absence of oculocephalic and suction reflexes⁹⁰¹. The body's minimum temperature must be 36 degrees Celsius⁹⁰². Ancillary tests are required in the case of confounding factors or when clinical criteria cannot be established. Clinical criteria should use oculocephalic rather than oculovestibular reflexes for infants aged 30 days to one year. A second examiner should confirm the diagnosis, but no time interval is specified. Ancillary tests are only required in cases of clinical ambiguity or confounding variables⁹⁰³. If organ donation is intended for children over the age of one, a second examiner must confirm the diagnosis, as required by law. No time gap is required. Although brain death instances account for only 1% to 2% of all deaths in the United States each year, many clinicians

⁸⁹⁷ Wijdicks EF. Brain death worldwide: accepted fact but no global consensus in diagnostic criteria. *Neurology*. 2002;58(1): 20-25.

⁸⁹⁸ Nakagawa TA, Ashwal S, Mathur M, Mysore M. Guidelines for the determination of brain death in infants and children: an update of the 1987 task force recommendations. *Pediatrics*. 2011;128(3):e720-e740.

⁸⁹⁹ Virginia statute, section 54-1-2972; 1997.

⁹⁰⁰ Wijdicks EF, Smith WS. Brain death in children: why does it have to be so complicated? *Ann Neurol*. 2012;71(4):442.

⁹⁰¹ Shemie SD, Doig C, Dickens B, et al. Severe brain injury to neurological determination of death: Canadian forum recommendations. *CMAJ*. 2006;174(6):S1.

⁹⁰² Florida statute annotated, section 382.009; 1997.

⁹⁰³ New Jersey statute annotated, 26-6A-5, suppl. 1994; 1987.

remain uneasy with the brain death determination process. Furthermore, brain death patients account for the majority of organ donors, adding another layer of complexity to the bedside clinician's considerations timely declaration and continued resuscitation of the potential donor who is brain-dead, as well as clear barriers between treating physicians and the local Organ Procurement Organization (OPO)⁹⁰⁴. In the United States, OPOs must be told ahead of time about the ongoing brain death determination process, but they cannot contact family members until the process is completed. Laws and regulations vary by state and country, but the important fact remains that the physicians involved in the brain death determination must not be affiliated with or work for the organ procurement company, nor must they be members of the organ recovery team, in order to eliminate any possibility of secondary gain⁹⁰⁵.

4.3 BRAIN DEATH IN ADULTS

Although the idea of brain death is widely accepted, Wijdicks' investigation of 80 nations revealed significant disparities in the processes used to diagnose brain death in adults. Differences were discovered between these countries in the presence of legal standards on organ transplantation and practice guidelines for determining brain death in adults, the time of observation and required expertise of examining physicians, and the number of physicians required to declare brain death. Interestingly, in the United States, these disparities exist between states and even different health care organizations.

For example, while the majority of states recognize total brain death as the governing definition of death, only 36 states and the District of Columbia have adopted the UDDA. The remaining US states have similar statutes, although the distinctions are significant. Virginia

expressly seeks a neurology specialist. Florida requires two physicians: one must be the treating physician and the other a board-eligible or board-certified neurologist, neurosurgeon, internist, pediatrician, surgeon, or anesthesiologist. In addition, New York and New Jersey have amended their laws to accommodate religious objections. These modifications oblige clinicians to fulfill these wishes and provide medical care despite indications of loss of brain function.

In most jurisdictions, one physician's conclusion is adequate; however, statutes in California, Alabama, Iowa, Louisiana, Florida, Virginia, Kentucky, and Connecticut require independent confirmation by another physician. In Alaska and Georgia, a certified nurse has the ability to proclaim death based on the legislative criteria, with physician certification within 24 hours. In Virginia, registered nurses have little jurisdiction. Despite these discrepancies, the consensus is that brain death occurs when brain stem reflexes, motor responses, and respiratory drive are missing in a normothermic, non-drugged coma patient with an irreversible large brain injury and no contributing metabolic derangements.

In other words, the determination of brain death is founded on simple principles: the existence of an unresponsive coma, the absence of brain stem reflexes, and the lack of respiratory drive following a CO₂ challenge. The American Academy of Neurology's 1995 practice guidelines underlined these three clinical findings. These recommendations were further evaluated in the AAN 2010 update on adult brain death criteria. Despite these two articles, considerable practice variation persists. Prerequisites, the lowest allowed core temperature, and the number of needed examinations, among other things, varied between top US hospitals. The following practical guidance for determining brain death is based on the 2010 AAN recommendations and is opinion-based. It is intended as a useful tool and a reminder that the brain death determination is a stepwise process, which

⁹⁰⁴ New York Compilation Codes Regulations, Rules 7 REGS, title 10, section 400.16 (d), (e)(3); 1992.

⁹⁰⁵ Virginia statute, section 32.1–162.7 and section 32.1–162.

must include the following 4 steps—preclinical testing, clinical examination, apnea testing, and ancillary testing.

4.4 BRAIN DEATH IN PREGNANCY

The medical, legal, and ethical complexities surrounding brain death increases with determination of brain death in pregnant patients, with additional considerations such as the determination of fetal viability, the risks and costs of continued maternal somatic support, and the dignity and autonomy of the pregnant patient or the surrogate decision maker balancing with the fetus's right to life⁹⁰⁶. Prolonged maternal somatic support requires exceedingly complex management of several medical conditions that arise with brain death, including hemodynamic instability, pituitary dysfunction, diabetes insipidus, neurogenic pulmonary edema, infection, and nutritional depletion. These complications and their management have an uncertain impact on fetal development. While most states have not enacted laws that specifically address the brain-dead pregnant patient, over 30 states have statutes that deny the withdrawal or withholding life-sustaining treatment from pregnant patients or invalidate legal advanced directives during pregnancy. Some require the continuation of support dependent on fetal viability and likelihood of survival. At this time, only the states of Minnesota and Oklahoma have specific laws that require following the wishes of the pregnant patient or their proxy.

Inconsistency in the legal treatment of the brain-dead pregnant patient is highlighted in the 2013 Texas case of Marliese Muñoz, who was 14 weeks pregnant when she was declared brain dead due to anoxia secondary to a pulmonary embolism⁹⁰⁷. The hospital continued cardiopulmonary support in accordance with state law that prohibits withdrawal of life-sustaining treatment from a pregnant patient, despite Muñoz's family's claim that Muñoz had

previously expressed that she would not have wanted cardiopulmonary support. After 2 months, the court ruled that life-sustaining treatment only pertained to pregnant patients who were alive and ultimately ordered the withdrawal of support. The AAN defers to the surrogate decision makers' wishes when considering organ-sustaining support in a brain-dead pregnant patient, granting accommodation to prolong use of organ-sustaining technology when requested, but also to uphold the surrogates' request to withdraw support particularly if fetus is not of viable gestational age or has sustained brain injury. The American College of Obstetrics and Gynecologists Committee on Ethics released a statement in 2015 that the dignity and autonomy of the dying person should be respected regardless of pregnancy status and that technological support is ethical if the surrogate decision maker requests support for additional fetal development on the pregnant patient's behalf⁹⁰⁸, a position reiterated by the International Federation of Gynecology and Obstetrics⁹⁰⁹.

CHAPTER V

DECLARATION OF BRAIN DEATH

5.1 THE VALIDITY OF THE AAN'S PRACTICE GUIDELINE FOR BRAIN DEATH DETERMINATION

The summit began with the subject of whether brain death symbolizes death of a person and whether the AAN practice guideline is the accepted medical standard for determining brain death. While the attendees acknowledged that a minority of them believe brain death is a legal fiction and that death does not occur until irreversible cardiopulmonary arrest, every attendee agreed that death determined by neurological criteria is equivalent to death determined by cardiovascular criteria. Cardiopulmonary death is defined as irreversible loss of circulatory and

⁹⁰⁶ Varelas P, Greer D, Lewis A. Pregnancy and brain death: lack of guidance in U.S. hospital policies. *Am J Perinatol*. 2016;33(14):1382–7. <https://doi.org/10.1055/s-0036-1582445>.

⁹⁰⁷ *Munoz v. JPS Hospital*. District Court, Tarrant County, Texas; 2014.

⁹⁰⁸ American College of Obstetrics and Gynecology. Committee Opinion No. 617: end-of-life decision making. *Obstet Gynecol*. 2015;125(1):261–7. <https://doi.org/10.1097/01.Aog.0000459869.98866.91>

⁹⁰⁹ Dickens B. Brain death and pregnancy. *Int J Gynecol Obstet*. 2011;115(1):84–5. <https://doi.org/10.1016/j.jigo.2011.07.002>.

respiratory function⁹¹⁰, whereas brain death is defined as irreversible loss of consciousness and brainstem function, resulting in the inability to breathe independently of artificial support and, ultimately, the demise and decay of all organ systems. Death is determined by the cessation of clinical function of the heart, lungs, or brain, rather than the death of every neuron or myocardial cell⁹¹¹. The attendees also agreed that the 2010 AAN practice guideline is the current standard for determining brain death, as there have been no recorded cases of neurological function recovery following brain death determination when the parameters are followed correctly⁹¹². To avoid false-positive results, the parameter is designed to be cautious and favor specificity.

5.2 BRAIN DEATH DECLARATION PROCESS

5.2.1 The Evaluation Team

In India, according to the Transplantation of Human Organs (THO) Act, 1994 (Sub section 6 of Section 3), 'brain stem death' refers to the stage at which all functions of the brain stem have permanently and irreversibly ceased. This is to be certified by a 'Board of Medical Experts' consisting of (1) The medical superintendent (MS)/In-Charge of the hospital in which 'brain stem' death has occurred, (2) a specialist, (3) a neurologist or a neurosurgeon nominated by the MS, from a panel approved by the Appropriate Authority, and the doctor under whose care the 'brain-stem' death has occurred. Amendments in the THO Act 2011 have allowed selection of a surgeon/physician and an anesthetist, if an approved neurosurgeon or neurologist is unavailable.

5.2.2 Evaluation Criteria

Criteria of brain death vary in different countries depending on the principal definition of brain-death, which could either be the death of all central neurological tissue with the complete loss of cerebral function; or, the irreversible loss of integrated neurological function, e.g., consciousness and the ability to breathe. In India, brain stem death was legalized in 1994, when The Transplantation of Human Organs (THO) Act was passed. The UK criteria for brain stem death is followed in our country. Brains of children younger than 5 years of age allow some functions to recover despite their clinical states, that would in adults be accepted as irreversible. It may be reasonable to declare brain death in children older than 3 months if a single electroencephalogram has demonstrated electro-cerebral silence.

Brain death should not even be thought of, until the following reversible causes of coma have been excluded. Intoxication (alcohol), drugs including muscle relaxants which depress the central nervous system (CNS), primary hypothermia, hypovolemic shock, as well as metabolic and endocrinal disorders should be ruled out. Hyponatremia and diabetes insipidus are more often the effects rather than the causes of brain death. The clinical diagnosis of brain death should be performed in three steps: (1) Establishing the etiology; (2) excluding potentially reversible syndromes that may produce signs similar to brain death; and, (3) demonstrating clinical signs of brain death including coma, brain stem areflexia and apnea.

For certifying brain death, the following need to be evaluated: Presence of irreversible coma; and, the cessation of spontaneous respiration confirmed with apnea tests, absence of pupillary light reflexes, corneal reflexes, doll's eye movements, gag reflex, cough reflex (tracheal), eye movements on caloric testing bilaterally, motor response in any cranial nerve distribution, and motor response on stimulation of face/limb/trunk,

⁹¹⁰ Lewis A, Adams N, Varelas P, Greer D, Caplan A. Organ support after death by neurological criteria: results of a survey of US neurologists. *Neurology* 2016;87: 827–834.

⁹¹¹ Greer DM, Wang HH, Robinson JD, Varelas PN, Henderson GV, Wijdicks EFM. Variability of brain death policies in the United States. *JAMA Neurol* 2016;73:213–218.

⁹¹² Wijdicks EFM, Varelas PN, Gronseth GS, Greer DM. Evidence-based guideline update: determining brain death in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2010;74:1911–1918.

5.2.3 Criteria for Diagnosing Brain Death in Infants and Children

As children are more resilient than adults, a longer time between assessments, of greater than 6 hours, has been advocated. This varies according to the patient's age: Term to 2 months old: 48 hours, >2 months to 1 year: 24 hours, >1 year to <18 years: 12 hours, >18 year: As in adults. The diagnosis of brain death cannot be made in preterm infants of gestational age of less than 37 weeks. Hypotension, hypothermia, and metabolic disturbances should be treated and corrected prior to any evaluation. Assessments in neonates and infants should be performed by pediatric specialists with critical care training. Apnea testing is positive if there is presence of arterial $\text{PaCO}_2 \geq 20$ mm Hg above the baseline, and ≥ 60 mm Hg with no respiratory effort, during the testing period. If the apnea test cannot be safely completed, an ancillary study should be performed. Ancillary studies are deployed only when components of the examination or apnea testing cannot be completed safely, or there is uncertainty about the results.

5.3 Clinical Examination (Neurological Assessment)

5.3.1. Coma:

Patients must lack all evidence of responsiveness. Eye opening or eye movement to noxious stimuli is absent. Noxious stimuli should not produce a motor response other than spinally-mediated reflexes. Spinal reflex movements have been observed anyway from 13% to 79% of the brain-dead patients. Spinal reflexes can be present at the time brain death is established or they can reappear afterwards⁹¹³. Lazarus sign, a brief attempt of the body to flex at the waist, making it seem to rise, is the most dramatic and complex movement seen in patients with brain death. It is not very common and can be observed during an apnea test, an oculocephalic test, after a

painful stimulus, and after removal of a ventilator. The other reflex movements observed are finger and toe jerks, extension at arms and shoulders, flexion of arms and feet, a slow turning of the head to one side, facial twitching, a persistent Babinski reflex, and tendon, abdominal, and cremasteric reflexes. An awareness of spinal reflexes may prevent delays in and misinterpretations of the brain-death diagnosis for both the physicians and the family.

5.3.2. Absence of brain stem reflexes:

Absence of pupillary response to a bright light is documented in both the eyes. Usually, the pupils are fixed in a midsize or dilated position (4–9 mm). Constricted pupils suggest the possibility of drug intoxication. When uncertainty exists, a magnifying glass should be used.

Absence of ocular movements using oculocephalic testing and oculovestibular reflex testing. Once the integrity of the cervical spine is ensured, the head is briskly rotated horizontally and vertically. There should be no movement of the eyes relative to head movement. The oculovestibular reflex is tested by irrigating each ear with ice water (caloric testing) after the patency of the external auditory canal is confirmed. The head is elevated to 30°. Each external auditory canal is irrigated (1 ear at a time) with approximately 50 mL of ice water. Movement of the eyes should be absent during 1 minute of observation. Both sides are tested with an interval of several minutes. Cold caloric test takes the place of classical oculocephalic testing in suspected or known C-spine injury.

Absent corneal reflex is demonstrated by touching the cornea with a piece of tissue paper, a cotton swab, or squirts of water. No eyelid movement should be seen.

Absence of facial muscle movement to a noxious stimulus. Deep pressure on the condyles at the level of the temporomandibular joints and deep pressure at the supraorbital

⁹¹³ Jorgensen EO. Spinal man after brain death. the unilateral extension-pronation reflex of the upper limb as an indication of brain death. Acta Neurochir (Wien). 1973;28(4):259-273.

ridge should produce no grimacing or facial muscle movement.

Absence of the pharyngeal and tracheal reflexes. The pharyngeal or gag reflex is tested after stimulation of the posterior pharynx with a tongue blade or suction device. The tracheal reflex is most reliably tested by examining the cough response to tracheal suctioning. The catheter should be inserted into the trachea and advanced to the level of the carina followed by 1 or 2 suctioning passes.

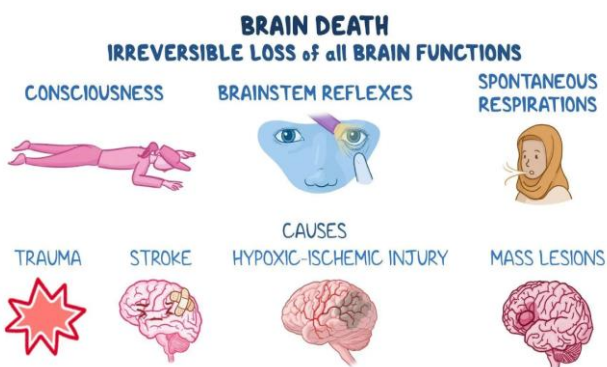


Image Courtesy: www.osmosis.org⁹¹⁴

5.4 Apnea Testing

Absence of a breathing drive is tested with a CO₂ challenge. Documentation of an increase in PCO₂ above normal levels is typical practice. It requires preparation before the test. Prerequisites: (1) normotension, (2) normothermia, (3) euvolemia, (4) eucapnia (PCO₂ 35–45 mm Hg), (5) absence of hypoxia, and (6) no prior evidence of CO₂ retention (ie, chronic obstructive pulmonary disease and severe obesity).

Procedure:

- 1) Adjust vasopressors to a systolic blood pressure of 100 mm Hg.

- 2) Preoxygenate for at least 10 minutes using 100% oxygen.
- 3) If the pulse oximetry oxygen saturation remains above 95%, take a baseline blood gas (pH, PCO₂, PaO₂).
- 4) Disconnect the patient from the ventilator.
- 5) Maintain oxygenation—for example, insert an insufflation catheter via the endotracheal tube and near to the carina level, delivering 100% oxygen at a rate of 6 L per minute. Excessive CO₂ washout can occur when oxygen flow exceeds 6 L/min. Monitor respiratory movements for 8–10 minutes.
- 6) Respiration is defined as abdomen or chest movements that may involve a short gasp. Abort if systolic blood pressure falls below 90 mm Hg. Abort if pulse oximetry shows oxygen saturation below 85% for more than 30 seconds.
- 7) Retry the surgery with continuous positive airway pressure (10 cm H₂O) or a T-piece and 100% oxygen at 12 L/min.
- 8) If no respiratory drive is seen, retest the blood gas (pH, PCO₂, and PO₂) after 10 minutes.
- 9) If there are no respiratory movements and arterial PCO₂ levels.
- 10) The apnea test result is positive if arterial PCO₂ rises by 60 mm Hg or 20 mm Hg above a known baseline normal arterial PCO₂.
- 11) The partial pressure of carbon dioxide increases at a rate of around 3 mm Hg every minute. If the test is inconclusive but the patient remains hemodynamically stable during the procedure, it may be repeated for a longer period of time (10–15 minutes) once the patient has been appropriately preoxygenated.

⁹¹⁴[https://www.google.com/imgres?imgurl=https://www.osmosis.org/_next/image?url%3Dhttps%253A%252F%252Fd16qt3wv6xm098.cloudfront.net%252FA35ruauxRP6Tw1M-xHi8-T0tQC-62A1W\\$%252F.jpg%26w%3D373840%26q%3D75&tbid=QQX6C-IsaW8xTM&vet=1&imgrefurl=https://www.osmosis.org/learn/Brain_death_Clinical_sciences&docid=704wKXYyaOPDFM&sw=1920&sh=1080&itg=1&hl=en-US&source=sch/x/im/m1/4dksgs=afa7d5a32ceb3160](https://www.google.com/imgres?imgurl=https://www.osmosis.org/_next/image?url%3Dhttps%253A%252F%252Fd16qt3wv6xm098.cloudfront.net%252FA35ruauxRP6Tw1M-xHi8-T0tQC-62A1W$%252F.jpg%26w%3D373840%26q%3D75&tbid=QQX6C-IsaW8xTM&vet=1&imgrefurl=https://www.osmosis.org/learn/Brain_death_Clinical_sciences&docid=704wKXYyaOPDFM&sw=1920&sh=1080&itg=1&hl=en-US&source=sch/x/im/m1/4dksgs=afa7d5a32ceb3160)

Sleep apnea or severe lung disease leading in persistent CO₂ retention may interfere with the clinical diagnosis of brain death, making the diagnosis impossible to make with certainty on clinical grounds alone, unless the patient's normal baseline PCO₂ is known. In that instance, consider the patient's baseline normal PCO₂ at the commencement of the apnea testing; if the PCO₂ rises by 20 mm Hg or more from that baseline, the apnea test results support the clinical diagnosis of brain death. In these circumstances, confirmation tests are recommended. The major challenge is identifying brain death in patients who are on extracorporeal membrane oxygenation devices⁹¹⁵. To assess brain death in these patients, apnea test can be performed without compromising oxygenation by decreasing (but not stopping) the sweep gas flow and increasing oxygen delivery through the membrane⁹¹⁶.

5.5 Ancillary Tests

A detailed clinical assessment is used to determine brain death. In clinical practice, electroencephalography (EEG), cerebral angiography, nuclear scan, transcranial Doppler (TCD), computer tomography (CT) angiography (CTA), and magnetic resonance imaging/magnetic resonance angiogram are now employed in adults. They are classified into two types: those that test the electrical function of the brain and those that assess cerebral blood flow. EEG, nuclear scan, or cerebral angiography are the recommended and most regularly used tests. These confirmatory tests are not required in the United States but can be utilized when there is doubt about the reliability of some aspects of the neurological examination or when the apnea test cannot be conducted. A thorough clinical examination,

when administered by a qualified examiner, should have diagnostic accuracy⁹¹⁷.

5.6 Electroencephalography

The American Clinical Neurophysiology Society defines brain death as electrocerebral inactivity or quiet. It is defined as no EEG activity over 2 mV while recording from scalp electrode pairs 10 cm or more apart with interelectrode impedances less than 10,000 Ohms (10 KOhms) but greater than 100 Ohms⁹¹⁸. In conclusion, the Society advises the following guidelines in suspected cases of brain death:

- 1) At least eight scalp electrodes should be used. Interelectrode impedance should be 100 to 10,000 Ohms.
- 2) The integrity of the entire recording system should be checked.
- 3) Maintain a minimum distance of 10 cm between electrodes.
- 4) To improve sensitivity, elevate it to at least 2 mV for 30 minutes and use proper calibrations.
- 5) The high-frequency filter setting should not fall below 30 Hz, and the low-frequency setting should not exceed 1 Hz. Electroencephalography should show a lack of sensitivity to strong somatosensory or audiovisual stimulation.

5.7 Cerebral Scintigraphy

The Brain Imaging Council of the Society of Nuclear Medicine believes that agents such as diethylenetriaminepentaacetic acid, glucoheptonate, and pertechnetate (with perchlorate blockade) are far less effective than ^{99m}Tc-labeled hexamethylpropyleneamineoxime and ethyl cysteinate dimer for assessing cerebral perfusion⁹¹⁹. The absence of isotope absorption

⁹¹⁵ Muralidharan R, Mateen FJ, Shinohara RT, Shears GJ, Wijidicks EF. The challenges with brain death determination in adult patients on extracorporeal membrane oxygenation. *Neurocrit Care*. 2011;14(3):423-426.

⁹¹⁶ Dosemeci L, Cengiz M, Yilmaz M, Ramazanoglu A. Frequency of spinal reflex movements in brain-dead patients. *Transplant Proc*. 2004;36(1):17-19.

⁹¹⁷ Wijidicks EF. The case against confirmatory tests for determining brain death in adults. *Neurology*. 2010;75(1):77-83.

⁹¹⁸ American Clinical Neurophysiology Society – 2006 – Guideline 3: Minimum Technical Standards for EEG Recording in Suspected Cerebral Death. www.acns.org/pdfs/Guideline%203.pdf. Accessed August 15, 2012.

⁹¹⁹ Donohoe KJ, Frey KA, Gerbaudo VH, Mariani G, Nagel JS, Shulkin B. Society of Nuclear Medicine Procedure Guideline for Brain Death

in the brain parenchyma supports the diagnosis of brain death. In conclusion, the Society advises the following guidelines in suspected cases of brain death:

- 1) Inject the isotope within 30 minutes of reconstitution.
- 2) Obtain 500,000 anterior and lateral planar image counts of the skull at several time points: immediately, 30–60 minutes later, and 2 hours.
- 3) Additional pictures of the liver showing uptake can be used to validate a correct intravenous administration (optional).
- 4) No radionuclide localization in the cerebral hemispheres' middle, anterior, or basilar arteries (hollow skull phenomena).
- 5) No tracer in the superior sagittal sinus (a small tracer can emerge from the scalp).

5.8 Cerebral Angiography

The absence of cerebral circulation is a crucial confirming diagnostic for brain death. In situations of brain death, cerebral angiography typically shows no blood flow at or beyond the carotid bifurcation or Circle of Willis. The test must adhere to the following guidelines:

- 1) Inject high-pressure contrast medium into the aortic arch to reach both anterior and posterior circulations.
- 2) Check for no intracerebral filling at the carotid or vertebral artery entry point to the skull.
- 3) External carotid circulation should be patent.
- 4) Filling of the superior longitudinal sinus may be delayed.

False-negative cerebral angiograms with normal-appearing blood flow in at least some intracranial blood arteries have been recorded

when intracranial pressure is reduced by surgery, trauma, and ventricular shunts, or in neonates with malleable skulls⁹²⁰.

Conventional 4-vessel cerebral angiography is still the "gold standard" imaging procedure, however CTA is emerging as an alternative. A 2-phase spiral CT protocol after 20 and 60 seconds after injecting an adequate amount of contrast medium (120–150 mL) would typically indicate the absence of arterial and venous opacification in brain death patients due to the cessation of cerebral blood flow⁹²¹. Further confirmation is still required.

In adults, auxiliary tests are not required for the clinical diagnosis of brain death and cannot replace a neurological examination. Physicians ordering auxiliary testing should be aware of the differences between tests and the possibility of false positives (for example, the test shows brain death but the patient does not fulfill clinical criteria). If clinical findings are inaccurate, clinicians may choose not to order additional testing and declare brain death. It is advised that hospitals implement brain death policies and provide a consistent method for declaring brain death. Appendix A is an example of a brain death declaration form from a teaching hospital in California. Time of death is the time the arterial PCO₂ reached the target value. In patients with an aborted apnea test, the time of death is when the ancillary test has been officially interpreted.

5.9 Transcranial Doppler

Transcranial doppler (TCD) is a very sensitive and safe method of diagnosing cerebral circulatory arrest that can be used as a confirmatory test in conjunction with EEG and angiography. Transcranial doppler evaluation of a brain death patient yields a "reverberating or oscillating" pattern of flow (normal arterial blood flow in systole and reversed flow in diastole due to the very high distal brain

Scintigraphy version 1.0, approved February 25, 2003. www.interactive.snm.org/docs/pg_ch20_0403.pdf. Accessed August 15, 2012.

⁹²⁰ Frampas E, Videcoq M, de Kerviler E, et al. CT angiography for brain death diagnosis. *AJNR*. 2009;30(8):1566-1570.

⁹²¹ Dupas B, Gayet-Delacroix M, Villers D, Antonioli D, Veccherini MF, Soullou JP. Diagnosis of brain death using two-phase spiral CT. *Am J Neuroradiol*. 1998;19(4):641-647.

resistance in brain-dead patients), resulting in the absence of net flow per unit of time. The echoing pattern may proceed to "no flow" in the later stages of brain death. Transcranial doppler is more extensively applicable than EEG, and can be utilized earlier and safer than angiography⁹²².

5.10 Pitfalls in clinical evaluation

The following conditions may interfere with the clinical diagnosis of brain death. Confirmatory tests are recommended. These conditions include severe facial trauma, preexisting pupillary abnormalities, toxic levels of sedative drugs, aminoglycosides, tricyclic antidepressants, anticholinergics, antiepileptics, chemotherapeutic agents, neuromuscular blocking agents, sleep apnea or severe pulmonary disease resulting in chronic retention of CO₂. The following clinical observations, if present, though compatible with the diagnosis of brain death, may be a source of confusion. Motor responses "Lazarus sign" may occur spontaneously during apnea testing, often during the hypoxic or hypotensive episodes, and are of spinal origin. They include spontaneous movements of limbs other than pathologic flexion or extension response and respiratory-like movements and should not be misinterpreted as evidence of brain stem function. Sweating, blushing, tachycardia, normal blood pressure without pharmacologic support or sudden increases in blood pressure, absence of diabetes insipidus, occasional presence of deep tendon reflexes, superficial abdominal reflexes, triple flexion response and Babinski response may also sometimes be present.

5.11 Pathophysiology of Brain Death

Severe damage to neuronal tissue leads to edema and increase in intracranial pressure (ICP). Elevated ICP reduces cerebral perfusion pressure and cerebral blood flow. A vicious cycle is established in which decreasing

cerebral perfusion and increasing ICP reinforce one another until blood no longer enters the cranial cavity and transtentorial herniation and coning at the foramen magnum occurs. This herniation crushes the brain-stem leading to permanent dysfunction. Late neuronal injury is explained by reperfusion associated with hypoxic-ischemic brain injury. Death is a continuous ongoing process, not an isolated event. Total loss of neurophysiological functions of the brain for more than 8 minutes confirms total and irreversible loss of brain function. Complete cardiovascular and autonomic uncoupling has been shown after brain stem death. Diffuse metabolic cellular injury due to lack of hypothalamic control, producing generalized metabolic and hypoxic lesions in all tissues also occurs. Hyponatremia and diabetes insipidus are more often the effect rather than the cause of brain death. Even with maximal support, cardio-respiratory deterioration leading to somatic death will occur within days, although persistence of the cardio-respiratory drive for prolonged periods, even over 100 days, has been reported. The medullary reticular formation (RF) contains the vital centers controlling heartbeat, breathing and circulation. The pontine RF contains centers for coordination of acoustic, vestibular, respiratory and cardiovascular processes. The midbrain RF contains centers for visuospatial orientation and eating behavior. As brain-stem is structurally and functionally very compact, even small lesions can destroy vital cardiac and respiratory centers, disconnect the cerebral cortex from the brain-stem, and damage sensory fibers from higher centers of consciousness, perception and cognition. Damage to the RF may lead to loss of cognition, persistent unconsciousness and coma. The brain stem, which includes the midbrain, pons and medulla, contains the nuclei of the last ten cranial nerves and ascending and descending tracts. The reticular activating system provides the anatomical and physiological basis for wakeful consciousness.

⁹²² Ducrocq X, Braun M, Debouverie M, Junges C, Hummer M, Vespignani H. Brain death and transcranial Doppler: experience in 130 cases of brain dead patients. J Neurol Sci. 1998;160(1):41-46.

5.12 Concerns in Diagnosing Brain Death

Clinical guidelines for determining brain death are not consistently validated by the presence of irreversible brain stem ischemic injury or necrosis at autopsy. They do not, therefore, completely exclude the reversible loss of integrated neurological functions in those certified as potential donors. Several critical brain structures remain viable and continue integrated neurological functioning after clinically determined brain (stem) death occurs. These include electroencephalogram activity, and hypothalamic functions. A recent review of the clinical literature, found evidence that suggested preservation of the hypothalamic function in a substantial proportion of patients declared dead by the neurological criteria. Approximately half of the patients reported in the literature showed evidence suggesting the presence of osmoregulation via the regulated secretion of vasopressin (anti-diuretic hormone). A substantial proportion of patients were also secreting hypophysiotropic hormones originating in the hypothalamus. Patients with preserved cortical electrical activity or intracranial blood flow are considered to be dead in countries that utilize a brain stem criteria, but not dead in those where a whole-brain criteria is applied. Brain stem death has a lower burden of proof than whole-brain death. The latter can be viewed as an 'approximation' because the irreversible loss of all intracranial neurological functions is not confirmed during its clinical determination, Clinical observations indicate that heart-beating organ donors may occasionally have residual brain functions, including hormonal and neural responses to nociception and pain during the procurement process. Surgical procurement, which is performed on donors without general anesthesia induces hemodynamic responses in donors Wijdicks and Pfeifer studied 41 brain dead patients, mostly young donors declared brain dead by clinical examination, within 24 hours of blunt-force traumatic brain injury. Although neuronal ischemic changes were

frequently profound, a respirator brain with extensive ischemic neuronal loss and tissue fragmentation was not observed. They concluded that the neuropathologic examination is not diagnostic of brain-death.

5.13 Ethical Issues in Declaring Brain Death

The DDR is the formalization of the widely held belief 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, an act that would certainly kill them. The DDR is neither a law nor a regulation it is a description of an ethical norm: an organ donor must be dead before vital organs are removed.

5.14 Medico-Legal Implications in Certifying Brain Death

To a large extent the medico-legal implications of certifying brain death depends on the statutes prevailing in individual states and its interpretation on a case-by-case basis. In one instance in Texas, the husband of a brain dead patient asked that she be removed from physiological support, but the hospital refused, as the patient was 14 weeks pregnant at the time. The Texas Advance Directives Act, like similar laws in several other states, includes a provision prohibiting the withdrawal of life-sustaining treatment from a pregnant patient. The hospital interpreted this law as applying to the patient and thus refused to discontinue treatment. The husband filed a lawsuit, and the court ruled that the Texas Advance Directives Act did not apply because the patient had been determined to be legally dead. Thus, mechanical support could not be considered life-sustaining, and the court ordered the hospital to discontinue physiologic support, with which the hospital complied, though by that time two months had passed since her initial admission. In another instance, the parents of a 13-year old child refused to accept the hospital's decision to discontinue mechanical ventilation following brain death as the heart was still beating. They argued that the California statute recognising brain death,

violated their religious beliefs. The court upheld the caregivers contention. 15 months later, the patient was residing in an apartment with home ventilator care in New Jersey. Autonomy, properly understood, is the right to avoid unwanted intrusions rather than a right to have any medical treatment, however futile or cost ineffective. The process implies that once a person is brain dead, it is unethical to continue treatment.

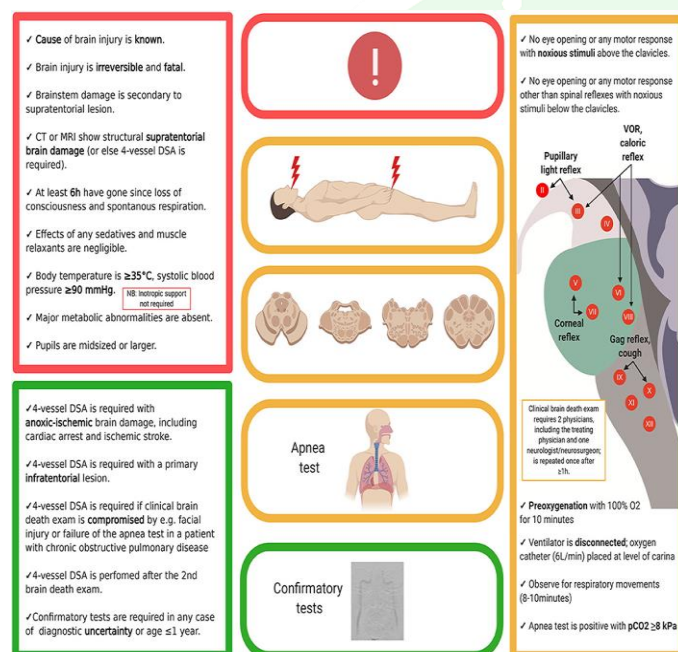


Image Courtesy: www.frontiers.in⁹²³

CHAPTER VI

NEUROLOGICAL CRITERIA

6.1 ACCEPTED MEDICAL STANDARD FOR DETERMINATION OF DEATH BY NEUROLOGICAL CRITERIA

The identification of accepted medical standards should be explicitly stated in legislation rather than left to individual trial court determinations. Adherence to this norm is necessary for both medical and legal determinations of death by neurological

criteria.⁹²⁴ Medical stakeholders accept the 2010 AAN and 2011 SCCM/AAP/CNS standards for determining death based on neurological criteria. In death-related statutes, legislators should specifically name these norms. Nevada's amended statute outlines these standards⁹²⁵, making it a model for other states to follow. It specifies that a declaration of brain death must be made: in accordance with the applicable guidelines set forth in: 1) 'Evidence-based guideline update: determining brain death in adults: report of the quality standards subcommittee of the American Academy of Neurology,' published June 8, 2010, by the American Academy of Neurology, or any subsequent revisions approved by the American Academy of Neurology or its successor organization; or 2) 'Guidelines for the determination of brain death in infants and children: an update of the 1987 task force recommendations,' published January 27, 2012 by the Pediatric Section of the Society of Critical Care Medicine, or any subsequent revisions approved by the Pediatric Section of the Society of Critical Care Medicine or its successor organization⁹²⁶.

The Nevada legislature recognized the need for a process that allows the legal grounds for death to adapt alongside changes in medical standards. To accomplish this, the legislature referenced future editions of the two standards. Some state supreme courts may consider this approach to be an unconstitutional delegation of legislative power to a private organization, as it automatically adopts future changes to current professional standards without further legislative action. To address this concern, we recommend that state legislators consider two alternatives. The agency delegation strategy involves the legislature adopting current standards by statute (as Nevada did) but delegating the

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https://www.google.com/imgres?imgurl=https://www.frontiersin.org/files/Articles/543343/fneur-11-00736-HTML/image_m/fneur-11-00736-g002.jpg&tbid=M-cl5cKkr6V4LM&vet=1&imgrefurl=https://www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2020.00736/full&docid=rMSjj0aHC-pDJM&w=1074&h=816&hl=en-US&source=sh/x/im/m1/4&kgs=4654c68eb8dec1c0

⁹²⁴ Lewis, Bernat, Blosser, et al., *supra* note 5. However, despite acceptance of these standards, it is worth noting variability in institutional standards persists. See Greer, Wang, Robinson, Varelas, Henderson, Wijdicks, *supra* note 89.

⁹²⁵ In re Guardianship of Hailu, 361 P.3d 524 (Nev. 2015); Nev. Rev. Stat. § 451.007; Greer, Wang, Robinson, Varelas, Henderson, Wijdicks, *supra* note 89; *McMath v. California*, No. 4:15-06042 (N.D. Cal. 2015).

⁹²⁶ Nev. Rev. Stat. § 451.007.

authority to update them to a state administrative agency, such as the Board of Medicine, with appropriate limits⁹²⁷. This strategy avoids pre-binding a document with unknown content until the designated organizations act.

Accordingly, a statute adopting this agency delegation approach would state that a declaration of brain death must be made: in accordance with the applicable guidelines set forth in: (1) 'Evidence-based guideline update: determining brain death in adults: report of the quality standards subcommittee of the American Academy of Neurology,' published June 8, 2010, by the American Academy of Neurology, or (2) 'Guidelines for the determination of brain death in infants and children: an update of the 1987 task force recommendations,' published January 27, 2012 by the Society of Critical Care Medicine, American Academy of Pediatrics and Child Neurology Society, or (3) subsequent revisions of these guidelines that are recognized by the Board of Medicine to be accepted medical standards. This approach represents a commonplace delegation of regulatory authority to an administrative agency obligated to follow statutorily required lawmaking procedures and norms. Moreover, the legislature itself will have ample opportunity to substitute its own judgment for that of the agency if it chooses to do so. We endorse this approach⁹²⁸.

If the legislature were unwilling to delegate this authority to the Board of Medicine (or an equivalent regulatory agency), a more cumbersome approach could be used. Under what we will call the "notice and opportunity for legislative review" approach, the legislature would reserve the opportunity to review successor versions of the medical practice standards before they take effect. Using this approach, the state legislature would: (1) adopt the current versions of the standards, as did Nevada; (2) require the Board of Medical

Practice (or an equivalent state administrative agency) to monitor actions by the AAN and other collaborating medical organizations; (3) require that agency to notify the appropriate leaders of the legislative body whenever the standards have been updated by the AAN and their collaborating organizations; and (4) specifically declare that the revised standards will take effect within 90 days of such notice unless the legislature takes contrary action before the expiration of that period. Whether this "notice and opportunity to review" approach would be upheld by state courts remains to be seen, but it is more likely to be upheld than the Nevada approach.

6.2 STATUTORY LANGUAGE GOVERNING DETERMINATION OF DEATH BY NEUROLOGICAL CRITERIA

The UDDA's wording "all functions of the entire brain" contradicts accepted medical standards, which do not require pituitary/hypothalamic malfunction to certify death based on neurological grounds⁹²⁹. Although medical standards do not measure pituitary or hypothalamic function, research show that these functions are present in 10–91% of patients who are ruled dead by neurological criteria⁹³⁰. This is confusing because the UDDA states that death by neurological criteria must be based on irreversible cessation of all functions of the entire brain, including the brainstem. The UDDA language may not allow for a declaration of death while pituitary/hypothalamic function is still present⁹³¹. However, the writers of the UDDA do not appear to have intended the phrase all functions of the entire brain to include functions of the pituitary gland and hypothalamus; in their 188-page report, they cited 'coma' 120 times, 'brainstem' 22 times, and 'apnea' nine times. However, the Commission did not use

⁹²⁷ § 8.14-8.16 (2018 ed.).

⁹²⁸ Cf. Haw. Rev. Code s 327C-1(e) (requiring the Director of Health to periodically convene a committee to review the UDDA).

⁹²⁹ Wijdicks, Varelas, Gronseth, Greer, *supra* note 70; Nakagawa, Ashwal, Mathur, Mysore, *supra* note 70; Lewis, Bernat, Blosser, et al., *supra* note 5; President's Commission, *supra* note 17.

⁹³⁰ Shah, *supra* note 71; Bronheim, *supra* note 122; Fisher and Alexander, *supra* note 41; Ali, *supra* note 71; Wong, Tan, Goh, *supra* note 71; Zamborgs and Vyas, *supra* note 71.

⁹³¹ President's Commission, *supra* note 17.

any terminologies to define pituitary, hypothalamus, or hormonal activity. Nonetheless, this circumstance has raised concerns in the medical and legal professions that current medical standards do not meet the legal requirements for death by neurological grounds⁹³². To align clinical practice with legislative language, the phrase "all functions of the entire brain" is typically interpreted as referring to all central nervous system functions that support the overall functioning of the body⁹³³. This argument may not be supported by a court interpreting the UDDA's term "irreversible cessation of all functions of the entire brain," notwithstanding its intellectual appeal⁹³⁴. We believe that amending the UDDA is the safest course of action. There are two ways to do this. The first, most principled, and philosophically satisfactory approach to the problem is to amend the language to specify which functions are relevant and why. The term "all" should be replaced with "irreversible cessation of functions of the entire brain, including the brainstem, leading to unresponsive coma with loss of capacity for consciousness, brainstem areflexia, and the inability to breathe independently." The authors of the UDDA took a nuanced approach, pointing to the elimination of specific physiological processes as indicators of irreversible loss of heart or brain function. However, they ultimately rejected this method as overly technical⁹³⁵. The argument over "all functions of the entire brain, including the brainstem" highlights the need for a more technical approach to the UDDA's language.

6.3 LEGAL ACCEPTANCE OF NEUROLOGICAL CRITERIA

While death by neurological criteria has been a legal definition of death in all fifty states since the implementation of the UDDA, the

legitimacy of brain death determination has been questioned since initial implementation, especially following popular media reports of "brain dead" patients making recoveries. When updating the 2010 AAN guidelines, Wijdicks et al. found no peer-reviewed journal reports of patients who had regained neurological recovery after proper application of the AAN parameters⁹³⁶. In the decade since, case reports have been described of patients declared brain dead, who on further examination were noted to have some type of neurological function of uncertain origin⁹³⁷. Careful review of these case reports reveals incomplete and variable documentation of the confirmatory tests performed. Uncertainty of the proper application of AAN brain death guidelines makes retrospective interpretation of these cases impossible. In their 2019 position statement, the AAN reiterated that they were "not aware of any cases in which following these guidelines led to inaccurate determination of death with return of any brain function, including consciousness, brainstem reflexes, or breathing".

Recently, the validity of the AAN brain death guidelines was questioned in the 2015 Supreme Court of Nevada case of Aden Hailu, a 20-year-old who suffered intraoperative anoxic injury during an appendectomy. She was pronounced brain dead after she lost brainstem reflexes and showed no spontaneous respiration on apnea test. Her father filed a motion for a restraining order against the hospital from discontinuing organ support; the district court ruled against the motion, stating that Hailu met the AAN guidelines for brain death and was thus legally dead. The case was appealed to the Supreme Court of Nevada, who declared that the hospital had improperly determined Hailu as brain dead per Nevada statutes and reversed the lower court decision,

⁹³² *Id.*

⁹³³ See Dalle Ave and Bernat, *supra* note 72; *supra* notes 73-74.

⁹³⁴ *But cf.* In re Guardianship of Hailu, 361 P.3d 524 (Nev. 2015) (allowed to advance to trial on this question); *McMath* (same).

⁹³⁵ Lewis, Bernat, Blosser, et al., *supra* note 5. However, despite acceptance of these standards, it is worth noting variability in institutional standards persists. See Greer, Wang, Robinson, Varelas, Henderson, Wijdicks, *supra* note 89.

⁹³⁶ Wijdicks EFM, Varelas PN, Gronseth GS, Greer DM. Evidence-based guideline update: determining brain death in adults: report of the quality standards Subcommittee of the American Academy of neurology. *Neurology*. 2010;74(23):1911-1918. doi:10.1212/wnl.0b013e3181e242a8.

⁹³⁷ Dalle Ave AL, Bernat JL. Inconsistencies between the criterion and tests for brain death. *J Intensive Care Med*. 2018;0885066618784268. 10.1177/0885066618784268.

holding that the district court had failed properly to consider whether the AAN Guidelines adequately measured all functions of the entire brain including the brain stem, and questioned whether the AAN Guidelines were considered accepted medical standards by the medical community. In response, the Nevada state legislature amended their state UDDA to require the declaration of neurological death (DND) follow guidelines established by the American Academy of Neurology or the Pediatric Section of the Society of Critical Care Medicine, including future updates⁹³⁸. This represents the first-time state laws have stipulated the specific medical guidelines to be used in brain death declaration.

6.4 THE FUTURE OF LAWS ABOUT DEATH BY NEUROLOGICAL CRITERIA

After discussing the history and current status of death legislation based on neurological criteria, we will discuss how to overcome the ambiguities and variations in these findings. However, before doing so, it is important to describe the critical measures that the AAN is launching to ensure accuracy in the medical determination of death by neurological criteria and to restore public trust in brain death assessments.

Their actions include: (1) developing educational initiatives and credentialing processes for physicians performing brain death determinations; (2) advocating for uniformity and regulatory oversight of institutional brain death policies; and (3) encouraging collaboration between adult and pediatric physicians to develop a single standard for brain death determination⁹³⁹.

Legal professionals and policymakers should work together to enhance clarity and uniformity in state legislation on determining death, complementing the efforts of the medical community. This includes (1) addressing the aforementioned variation in the

statute language governing the determination of death; (2) identifying the "accepted medical standards" for making brain death determinations; and (3) providing a clear plan for dealing with family objections to the use of neurological criteria to determine death. To accomplish this, a Revised Uniform Determination of Death Act model is needed.

6.5 CHALLENGES TO DETERMINATION OF BRAIN DEATH BY NEUROLOGICAL CRITERIA.

6.5.1 THE RESPONSE TO OBJECTIONS TO DETERMINATION OF DEATH BY NEUROLOGICAL CRITERIA

Although the ethical, medical, and legal communities accept brain death as legal death, families may object to determining death using neurological criteria due to moral or religious beliefs, hope that a patient will recover, or a refusal to accept that a determination of brain death is the legal equivalent of a determination of cardiopulmonary death. These families frequently try to relocate a patient to another facility in order to avoid a brain death diagnosis and the cessation of life support⁹⁴⁰. The management of these objections in adult and pediatric patients varies by state, hospital, and practitioner⁹⁴¹. Failure to adequately handle these conflicts has resulted in a number of high-profile cases in the United States in recent years, in which families have challenged the legitimacy and accuracy of neurological criteria used to determine death. 1-5 Although the President's Commission's important 1981 report tried to offer a pattern for the statutory definition of death across the country, various states continue to define death. Brain death is legally regarded as death in all states, however the wording used in state legislation to determine death varies. Summit attendees expressed concern that a lack of consistency in both institutional policies and practices related

⁹³⁸ Revises provisions governing the determination of death, (1 October 2017, 2017).

⁹³⁹ ADD cites for these activities

⁹⁴⁰ Lewis A, Adams N, Varelas P, Greer D, Caplan A. Organ support after death by neurological criteria: results of a survey of US neurologists. *Neurology* 2016;87: 827–834.

⁹⁴¹ Lewis A, Adams N, Chopra A, Kirschen M. Organ support after death by neurological criteria in pediatric patients. *Crit Care Med* 2017;45:e916–e924.

to brain death determination and statutory definitions of death, among other factors, may have contributed to the recent surge in lawsuits involving the determination of death by neurological criteria. If the medical or legal community treats brain death inconsistently or differently than cardiac death, public trust in the employment of neurological criteria to proclaim death may be eroded⁹⁴².

6.5.2 MANAGEMENT OF FAMILY OBJECTIONS BEFORE DETERMINATION OF DEATH BY NEUROLOGICAL CRITERIA

The UDDA is silent on the requirement for permission prior to determining brain death. However, leaving this issue up to clinicians and judges has resulted in significant confusion and diversity. To ensure certainty and clarity, a few states have addressed notice and consent for brain death testing. New legislation in Nevada specifies that "a determination of death" is a clinical decision that does not require the consent of the person's authorized representative or the family member with the authority to consent or withhold consent." The Act does not specify whether families should be informed of the desire to undertake a brain death diagnosis. In New York, the criteria for determining brain death state that family members should be notified, although consent is not required. We agree with New York's approach. Families should be informed of the impending death determination, even if they do not have a say in the decision-making process. As a result, we advocate revising the UDDA to specify that "reasonable efforts should be made to notify a patient's legally authorized decision-maker before performing a determination of death by neurological criteria, but consent is not required to initiate such an evaluation⁹⁴³." This formula highlights the need of family awareness during brain death determinations,

although practitioners are not required to obtain permission to conduct assessments to determine a person's status.

6.5.3 MANAGEMENT OF RELIGIOUS OBJECTIONS TO DECLARATION OF DEATH BY NEUROLOGICAL CRITERIA

The UDDA does not address objections to using neurological criteria to pronounce death or withdrawing organ support after determining brain death. However, the Commission acknowledges that hospitals can accommodate family objections. There is a paucity of legal advice for dealing with family objections to using neurological criteria to pronounce death and withdrawing organ support, sometimes based on religious views. Currently, state regulations and legal rulings on managing these objections vary significantly, leading to inconsistent and unpredictable decisions by hospital administrators, ethics committees, and clinicians. How much accommodation of these objections should be permissible by law? There are four options. First, there is the approach taken in New Jersey, which prohibits providers from declaring death until irreversible cessation of circulatory and respiratory function has occurred if a patient has religious or moral beliefs that death by neurological criteria is not death. Second, there is the approach taken in California and New York, which does not impact the occurrence or time of death, yet encourages providers to "reasonably accommodate" religious objections. Third, there is the approach taken in Illinois, where providers are told that religious and moral beliefs should be taken into consideration when determining time of death. Lastly, states could take an approach not currently explicitly stated anywhere in the country, and declare that religious and moral beliefs should not be taken into consideration either when determining occurrence or time of death or when determining whether to continue organ support⁹⁴⁴.

⁹⁴² Lewis A, Cahn-Fuller K, Caplan A. Shouldn't dead be dead? The search for a uniform definition of death. *J Law Med Ethics* 2017;45:112–128.

⁹⁴³ 10 N.Y.C.R.R. § 400.16(d). New York State Department of Health and New York State Task Force on Life and the Law. Guidelines for Determining Brain Death (Nov. 2011), available at https://www.health.ny.gov/professionals/hospital_administrator/letters/2011/brain_death_guidelines.htm (last visited October 28, 2019).

⁹⁴⁴ Lewis, Adams, Chopra, and Kirschen, *supra* note 91; Lewis, Adams, Varelas, Greer, and Caplan, *supra* note 91; Lewis, Varelas, and Greer, *supra*

Ideally, legislatures in all 50 states would adopt a unified approach on how to handle religious objections to brain death judgments, harmonizing the process of proclaiming death across the United States. Such a national expert body might be charged with formulating clear guidance for practitioners on their legal and ethical obligations in the setting of religious objections to brain death with respect to (1) whether or not a brain death determination should be performed, (2) which (if any) treatments should be continued after brain death determination and how long they should be continued, (3) whether the time of death should be recorded as the time the death by neurological criteria determination was completed or the time of cardiopulmonary death, and (4) who is responsible to pay for treatment rendered after death by neurological criteria is established⁹⁴⁵. In the absence of a uniform national position on accommodation of religious objections in brain death determinations, at a minimum, each state must take steps to provide clear legal guidance on each of four aforementioned questions and address the inevitable conflicts that will arise when families seek to move a patient to a more accommodating state. Notably, this unfolding process will occur in the context of ongoing constitutional litigation.

CHAPTER VII

INDIAN LEGISLATION

7.1 POSITION OF BRAIN-DEATH IN INDIA

Around a quarter-century ago, India joined the ranks of countries that recognized brain death as a legal reality, paving the way for deceased donor organ donation and transplantation. This was accomplished by enacting the Transplantation of Human Organs Act (THOA) in 1994, which was later amended multiple times. Private and non-governmental

groups (NGOs) and institutions, such as the MOHAN (Multi-Organ Harvesting Aid Network) foundation, were the first to raise awareness of brain death as an entity and promote organ donation. Eventually, governmental institutions took over these initiatives, forming a pyramidal network known as the National Organ Transplantation Programme (NOTP). The National Organ and Tissue Transplant Organization (NOTTO) was also founded with the goal of overseeing the entire program, which is led by the Ministry of Health in India. Despite these eventual developments, India continues to lag far behind many other countries in terms of brain death declarations and organ donation. Whereas over 500,000 potential recipients await transplantation each year in the country, only approximately 8,000 deceased donor transplants are carried out each year. It is critical that the political, administrative, and medical communities examine this apparent gap and devise corrective measures to promote this program and save the lives of people in waiting.

7.2 CONCEPT OF BRAIN DEATH IN INDIAN LEGISLATIONS:

The Government of India's 1969 Registration of Births and Death Act included a definition of death. When THOA was passed in 1994, brain death was defined only in that statute, and the Government of India's Registration of Births and Deaths statute was not changed to incorporate it. In the United States, these two entities have merged to evolve a unified definition of death, termed under the Uniform Determination of Death Act (UDDA), 1981, USA, as "an individual who has sustained either (i) irreversible cessation of respiratory and circulatory functions, or (ii) irreversible cessation of all functions of the entire brain, including brainstem, is dead". As a result, many Indians, especially healthcare practitioners, continued to think about the duality and ambiguity of the form of death.

note 96; 10 N.Y.C.R.R. § 400.16; N.J. Rev. Stat. § 26:6A; Cal. Health & Safety Code § 1254.4; 210 Ill. Comp. Stat. § 85/6.24; In re Allen Callaway, No. DG-16-08 (Pondera County, Mont. 2016); In re Miranda Grace Lawson, No. CL16-2358 (City of Richmond Circuit Court, Va. 2016); *McMath vs. California*, 2015. No. 3:15-06042 N.D. Cal.

⁹⁴⁵ See *supra* Section II.F.; President's Commission, *sup*; *ra* note 17.

At present death is an important component in three different Laws in India:⁹⁴⁶

1. The Registration of Births and Deaths Act, 1969
2. Section 2(6) of BNS
3. Transplantation of Human Organs Act of 1994

The death certificate itself is available in 2 different formats:

1. The Registration of Births and Deaths Act, 1969
2. Transplantation of Human Organs Rules 1995

In 1994, India's government recognized brain death as a kind of death under the Transplantation of Human Organs (THO) Act for the purpose of organ donation. Unlike the usual definition of death, which requires only one doctor to certify death, with brain death, four doctors must declare death twice, six hours apart. The 'required request' law, enacted in 2014 as an addition to the THO Act, mandates ICU doctors and transplant coordinators to request organ donation in the event of brain death. In such cases, the family may agree to or deny organ donation.⁹⁴⁷ In India the definition of brain death is usually used in organ transplantation. Since a number of recipients look out for organ donors, once the doctor determines that the brain death of a patient, then the organ donation is focused. Thus, determining brain death has little legal implications in comparison to other countries. Organ donation assumes importance in India rather than determination of brain death. Organ donation on the basis of brain death and legislations relating to organ donation in a legal and time bound manner is emphasized.

The Transplantation of Human Organs Act of 1994 (hereafter referred to as "THOA") was based on a similar statute in England⁹⁴⁸. The act established a legislative framework for organ

donation, addressing the country's extensive black-market activities in the field. It defines "brain stem death" as the stage at which all functions of the brain stem have completely and irrevocably stopped. A 'Board of Medical Experts' will certify this, consisting of (1) the medical superintendent (MS)/In-Charge of the hospital where the 'brain stem' death occurred, (2) a specialist, (3) a neurologist or neurosurgeon nominated by the MS from a panel approved by the appropriate authority, and (4) the doctor who cared for the patient. Amendments to the THOA in 2011 allowed for the appointment of a surgeon/physician and an anesthetist if an approved neurosurgeon or neurologist was unavailable. It established stronger criteria for proving brain stem death, including the study of several neurological symptoms and the elimination of reversible causes. This was accompanied by an increase in the monetary and jail-time penalties for illicit donations and unethical behavior. However, the THOA only regards brain stem death as genuine death for the purpose of organ donation. Thus, if the patient's attendants deny organ transplantation, the pronouncement of death must adhere to the "Registration of Births and Deaths Act"⁹⁴⁹.

7.3 LACUNAE IN THE THOA

The trade in human organs has attained legal immunity mainly due to the misuse of Section 9(3) of the Act. The Act in Section 9(1) explicitly states that no human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative (Section 2(1) of the THOA defines near relative as spouse, son, daughter, father, mother, brother or sister) of the recipient. However, Section 9(3) of the Act states that a donor with the approval of the Authorization Committee can authorize the removal of organs before his death by reason of affection or attachment towards the recipient or for any other special reason.

⁹⁴⁶ Requirement for Uniform Declaration of Death as Legislation in India, <https://www.itnnews.co.in/indian-transplant-newsletter/issue49/Editorial-Desk-of-IITN-49-473.htm> (last visited Jun. 10, 2025).

⁹⁴⁷ Death, Brain Death, and Organ Donation: A Work in Progress, <https://www.ijccm.org/abstractArticleContentBrowse/IJCCM/21291/JJP/fullText> (last visited Jun. 10, 2025).

⁹⁴⁸ Transplantation of Human Organs Act, 1994. Act no. 44 of 1994. Govt. of India with Appendix.

⁹⁴⁹ Ganapathy K. Brain death revisited. *Neurol India* 2018; 66:308-15.

7.4 RATIONAL BASIS FOR A NEW LEGISLATION: CASES OUTSIDE THOA

The Transplant of Human Organs Act of 1994 was a watershed moment in the effort to improve organ transplant regulation. It got close to filling a legal hole in the practice of medicine by recognizing brain stem death as a gateway to organ donation, but then missed the mark. Mr. John Doe's case illustrates the repercussions of this legislative gap. In Mr. John Doe's case, the question that the law must answer is not "how to apply adequate treatment?" but rather "whether to apply it at all?"⁹⁵⁰ Unfortunately, the THOA offers no aid in this subject, and to make matters worse, it does not even begin the procedure for a formal pronouncement of brain stem death in cases when transplantation is denied. The necessity to recognize brain stem death as "death" under the law stems from two unresolved difficulties. First, in the current legal vacuum, doctors are in a risky position when deciding whether to maintain life support or not. The cessation of such support may result in legal implications for the hospital and its clinicians, including charges of criminal negligence and maybe murder⁹⁵¹. The second is the ethical quandary of whether it is justifiable to spend critical medical resources on people who have no possibility of recovery and are effectively dead. Neither of these fears is unwarranted. The "President's Council on Bioethics"⁹⁵² White Paper on "Controversies in the Determination of Death" continues to support total brain death. As a result, the United States refuses to accept brain stem death on its own. In 1981, the State of Connecticut had not yet adopted the Uniform Death Statute and instead relied on the common law definition of death, which is the cessation of respiration and

breathing. In 1979, it updated the 'Uniform Anatomical Gift Act' to allow brain-dead people to donate organs. However, for all other purposes, they could not be regarded deceased. This is remarkably similar to the predicament that THOA now offers. This is remarkably similar to the predicament that THOA now offers. In this case, Dr. Evans refused to remove the ventilator without a formal pledge of absolute immunity from the States Attorney⁹⁵³. Despite feeling sympathy for the doctor and his family, the States Attorney refused to file such a claim. He stated that he will investigate any complaints submitted against Dr. Evans. Although the judge refused to give legal immunity in the case, the parties struck an agreement that the doctor would not be prosecuted and that an adequate protocol be developed. This similar scenario demonstrates the second concern, which is a code of ethics⁹⁵⁴. The presiding judge in this case called in various medical and religious-ethics specialists to testify about the ethical validity of removing a patient's life support equipment. They testified that it was ethically sound considering the resources being used to support someone who was functionally dead. The concerns at the heart of a statute requiring "Do Not Resuscitate Guidelines" are practicalities and ethics, as demonstrated by the index case. Patients in persistent vegetative states (PVS) are deemed alive for similar reasons. They're awake, but not aware. Their working brain stem enables them to breathe, track eye movements, react to light, and so on. The PVS is very different from brain stem death and cannot be treated on the same concept.

CHAPTER VIII

ORGAN DONATION

8. BRAIN DEATH AND ORGAN DONATION

It has been quite a long time now that the deceased organ donation/brain death has

⁹⁵⁰ Paris JJ, Cummings BM, Moore MP Jr. 'Brain death, dead, and parental denial the case of Jahi McMath'. *Camb Q Healthcare Ethics* 2014; 23:371-82.

⁹⁵¹ President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death*. Washington, D.C: Government Printing Office; 1981. Available from: <http://www.euthanasia.procon.org/sourcefiles/PresCommDefiningDeath.pdf>. [Last accessed on 2022 Jun 31].

⁹⁵² The President's Council on Bioethics. Available from: <http://www.bioethics.georgetown.edu/pbce/reports/death/Controversies%20in%20the%20Determination%20of%20Death%20for%20the%20Web%20%282%29.pdf>. [Last accessed on 2019 Nov 26].

⁹⁵³ Evans DW. Brain death. Brain death is a recent invention. *BMJ* 2002; 325:598.

⁹⁵⁴ Coimbra CG. Implications of ischemic penumbra for the diagnosis of brain death. *Braz J Med Biol Res* 1999;32: 1479-87.

been popularized worldwide. Maintenance of circulation and respiration becomes possible with the advent of mechanical ventilator and other sophisticated instruments, even if the person's brain is damaged irreversibly. These are known as brain-stem death persons or beating cadavers⁹⁵⁵. Organs can be harvested or retrieved from them for transplantation. Harvesting organs for transplantation purposes from such persons is known as cadaver transplantation. Recently, determination of brain death has assumed importance for two reasons:

- Counseling relatives of the deceased for organs' donation
- Timely declaration of brain death can reduce prolonged unnecessary hospital stay and cut short hospital bills.

In India, THOA, 1994 amended in 2011 regulates the removal, storage, and transplantation of human organs/tissues for therapeutic purposes and prevents the commercial dealings of human organs⁹⁵⁶.

8.1 INTERNATIONAL FRAMEWORK WITH RESPECT TO ORGAN TRANSPLANTATION

8.1.1 Declaration of Istanbul

This declaration is based on the principles of the Universal Declaration of Human Rights. The primary focus of this declaration was to further donations and transplants across the globe through international alliances. This declaration also focused on the way in which people with low incomes are exploited for the purpose of organ transplantation. Through this declaration, the countries and organizations were urged to have stringent laws forbidding these unethical practices to have accountability and also to ensure equitable sharing of the benefits of transplantation.

8.1.2 The Madrid Resolution on Organ Donation and Transplantation

This resolution urged the significance of organ donation and transplantation and how these must be considered as a responsibility and part of the wellbeing of people. This resolution also highlights the nation's need to invest in the development of a healthcare system on the basis of its own resources. It is to be obtained for the population in that country and, where appropriate, through regional or international supervision and ethical cooperation. Action should start (1) locally; (2) be based on broader public-health policies that both reduce the burden of the illness on the population and make organ transplants more available; (3) enhance the cooperation between stakeholder groups involved; and (4) work on the basis of the guidance of WHO and the Declaration. The aim is to have a comprehensive framework that addresses the worldwide challenges caused by the growing health concerns amongst the population across the world and also to address the scarcity of organs.

8.1.3 Guiding Principles on Human Cell, Tissue and Organ Transplantation

These principles were endorsed by the World Health Assembly and came into effect in 2010. These principles have provided aid to legislation and policies across the world regarding organ transplants across the world. These principles aimed at providing an 'orderly, ethical and acceptable framework' for organ transplants.

⁹⁵⁵ Mathiwaran K, Patnaik AK, editors. Brain-stem death and transplantation of human organs act. In: Modi's Medical Jurisprudence and Toxicology. 23rd ed. Gurgaon, Haryana: LexisNexis; 2009. p. 249-62.

⁹⁵⁶ National Organ Transplant Program. Director General of Health Services India. [about 7 screens]. Available from: http://www.dghs.gov.in/content/1353_3_NationalOrganTransplantProgramme.aspx. [Last accessed on 2018 Jun 04].

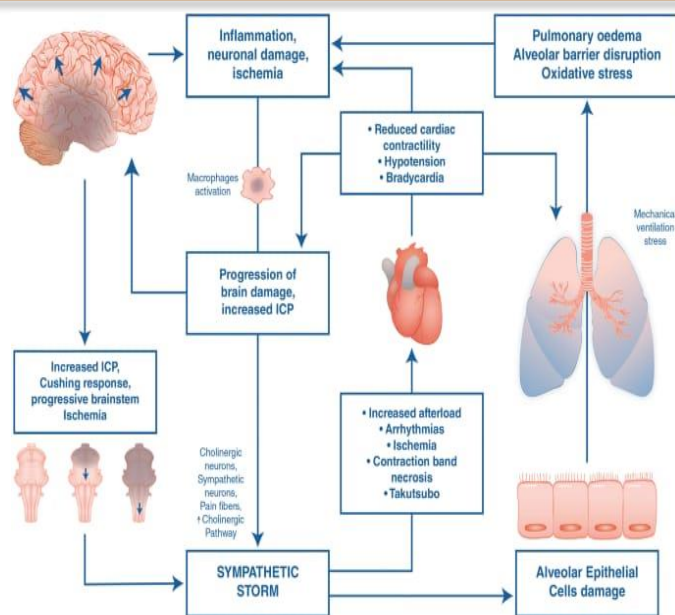


Image Courtesy: www.springer.com⁹⁵⁷

CHAPTER IX POSITION IN INDIA

9.1 ORGAN DONATION IN INDIA

Data from 2015 show that as against the demand for 1.75 lakhs of kidney transplants, there were only 5000 transplants done. Similarly, of 50,000 people dying of end-stage liver disease, only 1000 got their liver transplanted. Statistics are distressingly poor in case of transplantation of heart or lung⁹⁵⁸. Transplant rates for cornea are 1 in 25,000 when compared with 1 in 199 and 1 in 14,000 for the United States and Brazil, respectively⁹⁵⁹. Only 0.08% of Indians donate their organs when compared with 70%–80% of Spaniards and Belgians⁹⁶⁰. About 0.5

million people in India die every year due to nonavailability of organs⁹⁶¹. There are two systems for organ donation practiced worldwide, the family consent system and the presumed consent system. Countries like the United States, United Kingdom, Germany, and Netherlands follow family consent system where people sign up as organ donors, and their family's consent is required. ODR in these countries averages between 10 and 30 PMP. The more aggressive presumed consent system is adopted by countries like Singapore, Belgium, and Spain. This system permits organ donation by default unless the donor has explicitly opposed it during his or her lifetime. This system does not require family's consent. It is seen that the ODR in countries adopting presumed consent is double than the countries who have adopted family consent, averaging between 20 and 40 PMP. Inspired by this outcome, the doctors of All India Institute of Medical Sciences, New Delhi, have recently suggested starting "Presumed Consent" in India too, especially in cases of accidental fatalities⁹⁶².

The matter of health is placed under the state list under Entry 6 of the State list in the VII schedule of the Indian constitution. It is mentioned as "Public Health and Sanitation, Hospitals and Dispensaries." Article 252, read with Article 249 of the Constitution, is a special provision which confer power on the Parliament to legislate for two or more states by consent or by adoption of such legislation by any other state.

The central government, specifically the Ministry of Health and Family Welfare, has the responsibility to look into matters pertaining to the transplantation of organs. The Department of Health and Family Welfare is the department that deals with organ transplants out of the four departments that deal with other matters. The Health Care Directorate General (DGHS) is also

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https://www.google.com/imgres?imgurl=https://media.springernature.com/lw685/springer-static/image/art%253A10.1007%252Fs00134-019-05551-y/MediaObjects/134_2019_5551_Fig1_HTML.png&tbid=b8ZN-cfmrQhJ0M&vet=1&imgrefurl=https://link.springer.com/article/10.1007/s00134-019-05551-y&docid=yBMa6Y0rV1wKXm&w=685&h=469&hl=en-US&source=sh/x/im/m1/4&ks=0a3633f994a0a06d

⁹⁵⁸ Editorial. Life after Death: On Organ Donation Day, let's Resolve to Donate as well as set up an Effective Policy Mechanism. 13 August, 2015. Available from: <http://www.blogs.timesofindia.indiatimes.com/toi-editorials/life-after-death-on-organ-donation-day-lets-resolve-to-donate-as-well-as-set-up-an-effective-policy-mechanism> [Last accessed on 2017 Aug 30]

⁹⁵⁹ Gain P, Jullienne R, He Z, Aldossary M, Acquart S, Cognasse F, *et al*. Global survey of corneal transplantation and eye banking. JAMA Ophthalmol 2016;134:167-73.

⁹⁶⁰ TNM Staff. Five Myths Related to Organ Donation Busted. Available from: <http://www.thenewsminute.com/article/five-myths-related-organ-donation-busted-48167> [Last updated on 2016 Aug 13; Last accessed on 2017 Aug 30].

⁹⁶¹ About Organ Donation. Available from: <https://www.timesofindia.indiatimes.com/aboutorgandonation.cms>. [Last accessed on 2017 Aug 30].

⁹⁶² PTI. New Clause to Boost Transplant Cases: AIIMS. Available from: <http://www.assamtribune.com/scripts/spat.asp?id=2016/nov0216/BigPage3.jp>. [Last updated 2016 Nov 02; Last accessed on 2017 Sep 08].

attached to the above department's office. It is responsible for giving technical guidance on all issues relating to medical and public health and is active in the delivery of different health programmes. As announced, the ministry has considered steps such as a 50 per cent discount on second-class rail tickets and the provision of lifelong-free diagnostic checks and treatment at the hospital where the organ was donated.

The legal community and parliamentarians in India, in general, have not addressed the difficulties mentioned above. The closest they get is with "euthanasia," which is ethically, legally, and morally complex in its own right. However, the door to new legislation recognizing brain death appears to be opening up as a result of a succession of euthanasia cases. In this effort, the Supreme Court of India leads with the case of Aruna Shanbaug versus the Union of India. The court, citing US studies, stated that the brain is the most vital organ in the human body and that death is defined as the cessation of overall brain function⁹⁶³. It asserted that brain death is equivalent to human death. The state of Maharashtra took a step in the right direction by requiring that all cases of brain death be reported to the appropriate authorities and that suitable tests be used to diagnose brain death regardless of consent to transplant. It separated the determination from the transplantation procedure. The Kerala government, in a notification dated January 19, 2020, elected to provide a more expansive and liberal reading of the Registration of Births and Deaths Act⁹⁶⁴, including brain stem death in the definition of death. This was done in light of the challenges that lack of such acknowledgment causes. However, allowing this decision to separate governments means that medical science and the legislation do not coincide. As a result, a

revision to the Registration of Births and Deaths Act is required to ensure that resources, physicians, and family members are no longer subject to administrative red tapes and committees in every state in the Union. Of course, the solution to these challenges may not be found in the THOA. It might simply be the incorrect place to look for solutions. As previously noted, the answer appears to be in revising the Registration of Births and Deaths Act, which deals with death determinations similar to the Uniform Determination of Death Act in the United States. The reasons outlined above provide a philosophical and rational foundation for the need for such laws.

Transplantation of Human Organ Act, 1994:

The aims of the acts are twofold. One is to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes, and another is to prevent commercial dealings with human organs. This is the principal law in India governing organ donation and transplantation. The laws for organ donation and transplantation in India were non-existent before the passage of this Act, and malpractices were rampant. Parliament approved the amendment to the Act in 2011, and the laws were notified in 2014 as the Human Organs and Tissue Transplantation Rules 2014.

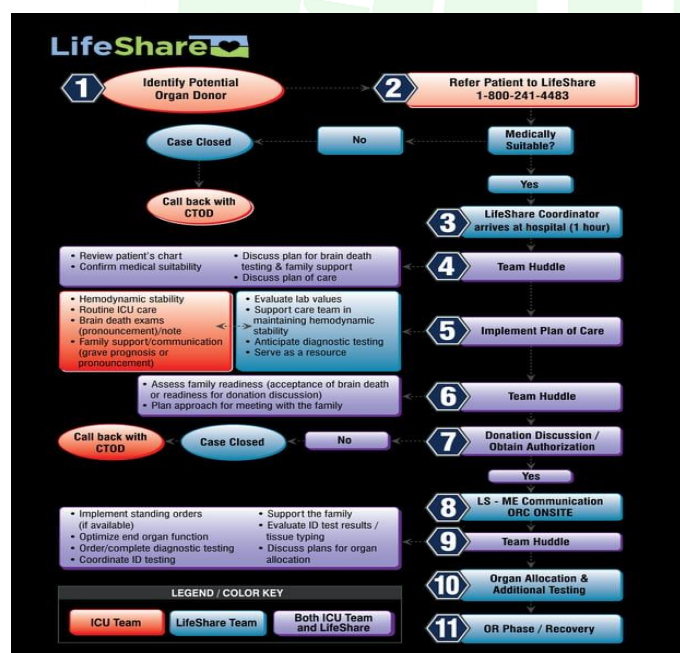
Brain Death:

'Brain-stem death' is defined as 'the stage at which all functions of the brain-stem have permanently and irreversibly ceased. This is one of the contentious provisions under the act. The act provides that allows the extraction of organs from persons who are brain-dead. This requires a declaration by the Board of Medical Experts as to "brain-stem death".³⁷ The following conditions are used as the definition of brain death and its statement – brain death: two doctors must be licenced for a span of 6 hours except for two of them, and the government's competent authority must appoint two of these doctors, one being a neurology specialist. If the family rejects such a

⁹⁶³ Deora H. Emerging legal issues in medicine and health care. Neurol India 2019; 67:626-7.

⁹⁶⁴ Brain Stem Death Certification Guidelines. Government of Kerala. Available from: <https://www.mohanfoundation.org/images/BRAIN-STEM-DEATH-CERTIFICATIONGUIDELINESKERALA.pdf>. [Last accessed on 2020 May 03].

donation, however, an additional issue can occur. Although 'brain death' is appropriate for organ donation under the Act, the individual is still not considered 'dead' before cardiac arrest or 'cardiac death' has occurred. This is because, although the Act describes death as 'brain death', the term 'death' has been defined differently under the Indian Penal Code, 1860 ("IPC"). In IPC, death means 'the death of a human being, unless the contrary appears from the context and in the Registry of Births and Deaths Act, 1969, 'Death' is when 'permanent disappearance of all evidence of life at any time after live-birth has taken place. Even if 'brain death' may have happened, it is then technically not appropriate to detach the patient from the ventilator and withhold treatment until the 'cardiac death' of the patient as the individual is alive even though with the help of a life support system.



Image

Courtesy:

www.lifeshareuniversity.org⁹⁶⁵

9.2 STATE-WISE ORGAN DONATION STATUS IN INDIA

Organ donation from deceased donors is slowly gaining momentum in India. In the year 2000, MOHAN Foundation took the lead in

setting up an organ sharing network, the Indian Network for Organ Sharing in the state of Tamil Nadu. This network facilitated the retrieval of 1033 organs and tissues. Many other states are also following Tamil Nadu with robust "Deceased organ donation and transplantation program." According to 2014 data, Puducherry has got highest ODR in India with 10.4 organ donation PMP, followed by Chandigarh with an ODR of 5.7 PMP. In terms of number of deceased organ donors, Tamil Nadu holds the number one spot with 136 donations during that year. Programs such as "Jeevandan" in Andhra Pradesh and "Zonal Transplant Coordination Center" in Maharashtra are already working for facilitating organ transplantation in these states. MOHAN Foundation has been spearheading efforts in Delhi NCR (National Capital Region) and Chandigarh with encouraging results. Kerala government has set up "Mrithasanjeevani" and the Kerala Network for Organ Sharing⁹⁶⁶, which have been running successfully since 2012. The Government of Rajasthan initiated the movement on organ donation with the setting up of the Rajasthan Network for Organ Sharing⁹⁶⁷. They have successfully retrieved 12 organs (liver and kidney) from five deceased donor within a period of 7 months since its inception in December 2014.

9.3 SCENARIO OF ORGAN DONATION NORTH-EASTERN PART OF INDIA

Organ transplantations were being performed in a few occasions in North-Eastern India, but the numbers are very nominal to talk about. Although a few local nongovernment organizations (NGOs) are being reported to be working toward generating awareness for organ donation, overall administrative negligence which can be summed up to lack of basic infrastructure, lack of trained individuals, and lack of government approved centers is probably putting the issue of organ donation to

⁹⁶⁶ Kerala Network for Organ Sharing, Mrithasanjeevani. Government of Kerala. Available from: <http://www.knos.org.in/>. [Last accessed on 2018 Mar 27].

⁹⁶⁷ Rajasthan Network for Organ Sharing. Government of Rajasthan. Available from: <http://www.rnos.org/>. [Last accessed on 2018 Mar 27].

⁹⁶⁵ https://www.lifeshareuniversity.org/uploads/4/0/5/4/40547033/brain-death-pathway-for-organ-donation-poster-01_orig.png

a state of dire straits in this region. It must be noteworthy to mention here that nothing substantial has been heard from the authorities of any of the seven North-Eastern states for adapting policies to facilitate organ donation till now. Thus, hundreds of patients still have to leave this region for transplantation every year. Raising awareness of organ donation in the present healthcare scenario in North-East India emerges as a challenge where even the basic health facilities are a far cry.

9.4 DIFFERENCES IN STATE LAWS

As highlighted by the lawsuit in Nevada, although all fifty states have adopted the UDDA recognizing neurological criteria for death, each state statute varies in their specific language and requirements. Some states such as Oklahoma require specific provisions in order to recognize brain death, such as attempts at cardiopulmonary resuscitation⁹⁶⁸. The state of Georgia includes civil/criminal immunity for people pronouncing death. Other differences include specific qualifications of the types of practitioners allowed to pronounce death, whether it be physicians only or whether trained advanced practice providers be allowed; additionally, some states require that the physician declaring brain death be a specialist in neurology or similar field. New Jersey is the only state that allows declaration of death solely on cardiorespiratory criteria if personal religious beliefs do not recognized brain death. There, a patient may not be declared dead legally even while meeting brain death criteria medically.⁹⁶⁹

The differences in state law are well illustrated in the 2013 Jahi McMath case, a patient who was ruled to be legally dead in California but was treated as living under New Jersey law. McMath was a 13-year-old who suffered anoxic brain injury from massive hemorrhage and cardiac arrest after a routine tonsillectomy at Children's Hospital Oakland.

She was declared brain dead at the treating hospital on December 12, 2013. Her family petitioned to continue cardiopulmonary support, and ultimately the Alameda County Superior Court ruled that she was legally dead. This decision was appealed to the United States District Court for the Northern District of California, with the eventual agreement that McMath's body with supportive equipment would be released to the custody of her mother. Her mother then transported McMath to a hospital in New Jersey, where she had a tracheostomy and percutaneous gastrostomy placed. In January 2018, when liver and kidney failure developed, ventilator support was removed, and a second death certificate was issued in the state of New Jersey. Since the McMath case, several lawsuits have arisen where families have sued to have the patient moved to New Jersey or other countries, such as Guatemala, where brain death criteria are not as strictly observed⁹⁷⁰.

A recent survey of neurologists found that most physicians are unaware of the differences in state laws. Identical laws for brain death declaration across all states could help ease some of the confusion surrounding and increase public acceptance of brain death. The AAN endorses development of uniform policies across states and institutions, with regulatory oversight by governing bodies to ensure proper training and credentialing of those making DNC declarations⁹⁷¹.

CHAPTER X

IMPORTANT CRITERIA FOR ORGAN DONATION

10.1 SUITABLE DONORS

Neonates, infants and children who have been certified and documented as neurologically deceased either through clinical testing or imaging (Determination of Neurological Death Policy) are suitable to be

⁹⁶⁸ Uniform Determination of Death Act, State of Oklahoma, 63–3122 (2000).

⁹⁶⁹ New Jersey Declaration of Death Act, 26:6A (1991).

⁹⁷⁰ Uniform Determination of Death Act, State of Virginia, 54.1–2972 (2016).

⁹⁷¹ Garrett MP, Williamson RW, Bohl MA, Bird CR, Theodore N. Computed tomography angiography as a confirmatory test for the diagnosis of brain death. *J Neurosurg*. 2018;128(2):639–44. <https://doi.org/10.3171/2016.10.JNS.161042>.

considered as potential organ donors. When end of life care is being considered, a routine referral to the NSW Organ and Tissue Donation Service (NSWOTDS) can be made. This may be prior to neurological death determination. Notification to the local donation team allows for preliminary discussions and assessment of suitability before donation is discussed with the family. Medical suitability of potential donors is assessed and determined by the NSWOTDS team in conjunction with transplant physicians. There is no expectation that the treating clinician should determine medical suitability. Optimising end-of-life care for the patient and the family should take precedent at all times.

10.2 FAMILY DONATION CONVERSATIONS (FDC)

After determination of neurological death, it is the responsibility for the ICU team to inform the parents/guardians of the death of their child. Time should be allowed for the family to process and understand this information and ask questions. The teams should be guided by the needs of the individual family. This conversation ideally, should be separate from a discussion regarding the possibility of organ donation. If organ donation is raised earlier by the family, it is at the discretion of the intensivist to continue or defer the organ and tissue donation conversation to a later time. A referral should be made as soon as possible to the DSN for consultation. The DSN can be notified of planned end of life discussions and may attend at the request of the treating team where appropriate. When the family has had time to process the information about the death of their child, a meeting should be arranged to discuss the planning of end-of-life care and the removal of life sustaining therapies.

A multidisciplinary meeting should be convened involving the intensivist, the primary medical / surgical team, DSM/DSN, nursing staff, social worker, pastoral care and other consulting services as relevant. The purpose of the meeting is to discuss and review any possible conflicts of interest and anticipate other clinical / ethical concerns or issues that

should be addressed in the family donation conversation. The possibility of organ and tissue donation is part of this planning and is offered to potential donor families. Families should be given the necessary time and space to consider the information and make a decision that is right for their family.

In the SCHN, donation should be raised in a collaborative approach as per the Best Practise Guidelines for Offering Organ and Tissue Donation in Australia and ANZICS Statement on Death and Organ Donation. There should be involvement of clinicians who have completed the core and practical Family Donation Conversation (FDC) workshops (medical DSM or DSN) in this discussion. Clear documentation in the medical record of any family donation conversations is required.

10.3 CONSENT

Consent for deceased organ and tissue donation is governed by the Human Tissue Act 1983⁹⁷² and makes provisions for obtaining consent and authorisation for donation.

Senior available next- of- kin (SANOK) for children:

- Parent of the child (both have equal standing)
- Sibling of the child (18y or over) if parent not available.
- Guardian of the child at the time of death where none of the above is available.

The process involved in organ donation must be explained to the parents in detail by the DSN. Consider using an interpreter when English is a second language to ensure the family understands what is being discussed and provide informed consent. Consent must be given for each organ and/or tissue to be removed.

⁹⁷² Human Tissue Act 1983 (NSW): <https://legislation.nsw.gov.au/view/html/inforce/current/act-1983-164> (accessed 15/4/24)

Parents will be provided with the following information in order to give informed consent:

- The possibility that some or even all of the organs may not be suitable for transplantation.
- Anticipated time frames for the donation process (i.e. 18–24 hrs.).
- Donation is an option to consider, and the family can change their mind at any stage and withdraw consent. Support is provided for families regardless of their donation decision.
- The steps in the process, including bloods required, continuation of life sustaining therapies and transfer to the operating theatre on the ventilator with a beating heart,
- which will stop during the surgery. Families can return to the ICU following surgery where they can spend time with their child.
- Whether the death requires notification to the coroner and, the coronial process.
- Organ donation does not have any benefits for their child.
- Prior to retrieval surgery, changes to medical treatment strategies (i.e. alterations in FiO₂, fluid bolus) may be required to ensure stability and organ function.
- Tissue donation (corneas, heart valves) can be an alternative to organ donation.
- Donation is carried out with respect and dignity for all involved.

Time must be given to a family to consider if organ donation is the right decision for them. Bloods for serology and tissue typing at the SEAL laboratory/ARCBS may be collected following verbal consent due to the length of processing time (6 – 8 hours). The DSN will organise the collection and transportation of these bloods.

If the child is <18 months of age or has been breast fed in the last 6 months, maternal bloods and AUDRAI will need to be completed for screening. When the family are ready, parents (or SANOK) are required to sign the Consent Form (SMRO20.030 Consent and Authority for Removal of Tissue after Death) with the DSN.

Authorisation from a SCHN Designated Officer (DO) is required following the certification of death to enable retrieval surgery to proceed. The DO must sign and verify consent has been given by the SANOK and authorise the organ donation and removal of tissue. The DO may want to be present for the consent and speak to the consenting family. The DSN will ensure the DO is informed as soon as possible. The DO for the SCHN campuses can be contacted via the switchboard.

10.4 POST-DONATION CARE

At the completion of surgery families may spend time with their child. This can be facilitated in the ICU or mortuary viewing room with assistance of DSN, ICU staff and social workers.

Family follow up

- 1) The ICU social worker will provide telephone follow-up with the bereaved family at least once during the first week following the child's death. The family will be contacted by the DSN 48 – 72 hours after the child's death or as negotiated, to provide support to the family, and outline the outcome of the donation process.
- 2) Parents are offered follow up, including the opportunity to meet with the treating team together with the Social Worker. The DSN/DSM may be also invited to this meeting. This enables parents to ask further questions or discuss unresolved concerns.
- 3) Telephone follow-up, with the offer of further meetings or counselling, should be continued for at least twelve months.

- 4) Parents of children who are organ donors are provided with support by the Family Support Coordinator through the NSW Organ & Tissue Donation Service. This program includes bereavement support, regular contact and information regarding donation outcomes, counselling services, support groups and anonymous exchange of letters.

Patient privacy

It is important to maintain the privacy of donor families and transplant recipients. The disclosure of identity or any information that could lead to the identification of the donor or recipient MUST NOT be relayed to the family. It is an offence in Australia to disclose information regarding the donor or recipient under The Human Tissue Act 1983 Section 37(2) and 37(3) and the Privacy Act 1988. The DSN and staff at OTDS will provide families with appropriate information about the transplant recipient outcomes.

Staff Support

The staff involved in the donation process will have the opportunity to receive information about the outcomes of the donation from the DSN in alignment with NSW privacy laws. An update will be sent to all areas involved in the donation process. The DSN will arrange a case review at an appropriate date and time following each donation. Attendance is voluntary. This provides feedback to all staff involved in the donation process and provide an opportunity to reflect upon the experience and collaborate as a team to discuss and identify areas for improvement for future donations. If further support is required for staff, engagement with the Employee Assistance Program (EAP) is encouraged.

Education

Education is provided by:

- **SCHN DSN (CNC2)** – regular education sessions throughout SCHN (Critical care/OT/wards/BC/NETS). Replicated on both sites– now face to face. Organised via education

teams in units/wards. Post donation case reviews provided for units involved and OT staff post donation. Standing item on PICU M&M/ CICU Consultant meeting to provide feedback and discussion. GNN consultant updates as required.

- **NSWOTDS and SCHN DSN:** The Organ and Tissue Donation Awareness Course (IDAT) is held at CHW and SCH 2nd yearly for staff (Nationally funded.) Staff can also attend course at other LHD's and information circulated in critical care areas throughout SCHN regarding this. Peri operative Nursing Donation 1 day course (Nationally funded) also held at CHW. SCH are covered by the POW OT scheduled course.

CHAPTER XI

LIABILITY AND JUDICIAL DECISIONS

11. MEDICAL NEGLIGENCE

11.1 Medical Professionals in Criminal Law

The criminal law has invariably placed the medical professionals on a pedestal different from ordinary mortals. The Indian Penal Code enacted as far back as in the year 1860 sets out a few vocal examples. Section 26 in the Chapter on General Exceptions provides exemption for acts not intended to cause death, done by consent in good faith for person's benefit. Section 30 provides for exemption for acts done in good faith for the benefit of a person without his consent though the acts cause harm to a person and that person has not consented to suffer such harm. There are four exceptions listed in the Section which is not necessary in this context to deal with. Section 31 saves from criminality certain communications made in good faith. To these provisions are appended the following illustrations:-

Section 26

A, a surgeon, knowing that a particular operation is likely to cause the death of Z, who suffers under a painful complaint, but not intending to cause Z's death and intending in good faith, Z's benefit, performs that operation

on Z, with Z's consent. A has committed no offence.

Section 30

Z is thrown from his horse, and is insensible. A, a surgeon, finds that Z requires to be trepanned. A, not intending Z's death, but in good faith, for Z's benefit, performs the trepan before Z recovers his power of judging for himself. A has committed no offence.

A, a surgeon, sees a child suffer an accident which is likely to prove fatal unless an operation be immediately performed. There is no time to apply to the child's guardian. A performs the operation in spite of the entreaties of the child, intending, in good faith, the child's benefit. A has committed no offence.

Section 31

A, a surgeon, in good faith, communicates to a patient his opinion that he cannot live. The patient dies in consequence of the shock. A has committed no offence, though he knew it to be likely that the communication might cause the patient's death. It is interesting to note what Lord Macaulay had himself to say about Indian Penal Code. We are inclined to quote a few excerpts from his speech to the extent relevant for our purpose from "Speeches and Poems with the Report and Notes on the Indian Penal Code" by Lord Macaulay (Houghton, Mifflin and Company, published in 1874).

"Under the provisions of our Code, this case would be very differently dealt with according to circumstances. If A. kills Z. by administering abortive to her, with the knowledge that those abortive are likely to cause her death, he is guilty of voluntary culpable homicide, which will be voluntary culpable homicide by consent, if Z. agreed to run the risk, and murder if Z. did not so agree. If A causes miscarriage to Z., not intending to cause Z's death, nor thinking it likely that he shall cause Z's death, but so rashly or negligently as to cause her death, A. is guilty of culpable homicide not voluntary, and will be

liable to the punishment provided for the causing of miscarriage, increased by imprisonment for a term not exceeding two years. Lastly, if A took such precautions that there was no reasonable probability that Z's death would be caused, and if the medicine were rendered deadly by some accident which no human sagacity could have foreseen, or by some peculiarity in Z's constitution such as there was no ground whatever to expect, A. will be liable to no punishment whatever on account of her death, but will of course be liable to the punishment provided for causing miscarriage.

11.2 JUDICIAL DECISIONS

11.2.1 THE CASE OF JAHİ MCMATH

These observations address popular objections to Jahi McGrath's killing in the US public debate. Jahi McGrath, a teenager, was certified brain-dead. The family refused to remove the ventilator, claiming that their daughter was healthy and alive, with a beating heart, warm body, and legs that pushed back slightly when touched⁹⁷³. However, Jahi McGrath had beyond the point of no return and was pronounced dead shortly after being transferred to another hospital. This explanation of death as a process assisted lawmakers in responding to a far greater objection: that it is a doctor's responsibility to save lives and that a doctor cannot authorize the certification of death. The question in circumstances like Mr. John Doe's described in this article is whether a person 'is' dead. The answer should be that the patient has passed the "no return" point⁹⁷⁴.

The case of *State v. Williams*⁹⁷⁵ illustrates why it is essential for courts to understand the proper meaning of brain death. In *Williams*, the Supreme Court of Georgia revealed a very poor understanding of the concept of brain death. A defendant charged with murder had demurred to the indictment on

⁹⁷³ Lewis A. Reconciling the case of Jahi McMath. *Neurocrit Care* 2018; 29:20-2.

⁹⁷⁴ Shewmon DA. Truly Reconciling the case of Jahi McMath. *Neurocrit Care* 2018; 29:165-70.

⁹⁷⁵ *State v. Williams*, 247 Ga. 200, 275 S.E.2d 62 (1981).

the grounds that she was deprived of information essential to her defense. She claimed that it was not clear from the face of the indictment "whether the indictment alleges death at the point of cessation of heartbeat, at the point of brain death, or perhaps later at a point of [absolute cessation of the functions of the brain, the circulatory and respiratory organs]. Although the opinion does not say, one assumes that the state was prepared to produce a dated death certificate indicating the time of death. Even so, the trial court had sustained the demurrer and the supreme court affirmed. The reason that the Williams case is disturbing is that the court seemed to assume that the time of death under the common law standard and under the brain death standard could be hours, perhaps days, apart. The victim in Williams had suffered a fatal heart attack that went untreated because the defendant had allegedly turned-off the victim's cardiac monitor warning device. Under those facts, the Georgia court should have known that the victim's brain would have been dead within a few minutes of the heart failure. "Perhaps the failure was the states, since the opinion does not discuss the state's theory of the case. Williams is also disturbing because Georgia, unlike many states, has enacted a brain death statute⁹⁷⁶. The court relegates the statute to a footnote, however, and does not examine its application to the case. The point is that even though legislatures may enact brain death statutes, courts still need to address brain death cases with care and scholarship.

11.2.2 *State v. Shaffer*⁹⁷⁷

In *Shaffer*, the appellant had been convicted of first-degree murder and other crimes. He claimed that the murder conviction was invalid because the alternative definitions of death in the Kansas statute rendered the statute unconstitutionally vague. The Supreme Court of Kansas rejected the appellant's contention, holding that: "The alternative test is

based on practical medical considerations in keeping with advanced medical technology. There is no constitutional requirement that a single standard be used." The significance of this holding is that the alternative definitions of death contained in the Uniform Determination of Death Act are, like the Kansas alternative definitions, constitutionally valid. The appellant in *Shaffer* also argued that the Kansas statute was unconstitutionally vague because the statutory phrase "ordinary standards of medical practice" was too imprecise. The court also rejected this contention, since "it was for the jury to determine whether the medical standards required. had been met." This holding is also significant since the Uniform Determination of Death Act provides that, "A determination of death must be made in accordance with accepted medical standards." In a later case⁹⁷⁸, the Kansas Supreme Court expressly rejected the proposition that the court should require physicians to follow the Harvard criteria⁹⁷⁹. The court explained: "Further attempts to define the phrase would merely result in confusing an otherwise understandable phrase⁹⁸⁰." The phrase is deliberately general in scope to allow for inevitable developments in medical techniques and criteria used to assess brain death.

11.2.3 *People v. Vanderford*⁹⁸¹

In *Vanderford*, the other case involving a constitutional attack on a brain death statute, the Court of Appeals of Michigan deflected a challenge that the Michigan brain death standard—"irreversible cessation of spontaneous brain function"—was too vague⁹⁸². Rather than reaching the merits of the appellant's theory of vagueness, the court held that the appellant lacked standing on the issue because "even if the statute were found unconstitutional, defendant's conviction would stand. The appellant, who had been convicted of involuntary manslaughter, contended that the

⁹⁷⁶ GA. CODE ANN. § 88-1715.1 (1982) (based on the ABA's 1975 Model Definition of Death Act discussed *supra* notes 29-33 and accompanying text).

⁹⁷⁷ *State v. Shaffer*, 223 Kan. 244, 574 P.2d 205 (1977).

⁹⁷⁸ *State v. Shaffer*, 229 Kan. 310, 624 P.2d 440 (1981).

⁹⁷⁹ *I. d.* at 318, 624 P.2d at 446-47.

⁹⁸⁰ *Id.* at 319, 624 P.2d at 447.

⁹⁸¹ *People v. Vanderford*, 77 Mich. App. 370, 258 N.W.2d 502 (1977).

⁹⁸² 77 Mich. App. at 372, 258 N.W.2d at 503.

doctors who treated the victim may have caused the victim's death by improperly removing the victim from a respirator. The court held that the appellant's conviction would stand even if the doctors had erred because "intervening medical error is not a defense to a defendant who has inflicted a mortal wound upon another⁹⁸³." The Michigan statute, based on the Capron-Kass proposal, thus escaped constitutional review. Vanderford is significant because it raises the issue of precision in the definition of brain death. Although the Capron-Kass definition is probably not unconstitutionally vague when read in conjunction with the requirement of "ordinary standards of medical practice," the definition in the Uniform Determination of Death Act—"irreversible cessation of all functions of the entire brain, including the brain stem"—is more precise. Since precise meaning is critical in this area, the Uniform Determination of Death Act enjoys a qualitative advantage over the Capron-Kass model.

In *Kuldeep Singh v State of Tamil Nadu*⁹⁸⁴ directed as follows: (1) All Authorization Committees shall, in terms of this judgement require the applicants to furnish their income particulars for the previous three financial years and the vocations; (2) The presence of an administrative official in the Authorization Committee would be helpful in deciding the issues more effectively because the Authorization Committee has to decide both on the medical angle regarding need for transplantation, and the existence or otherwise of the essential ingredients to be established under Sub-section (3) of Section 9 of the Act; (3) It would be appropriate for the legislature to accordingly amend the rules so that requirement for disclosing incomes and vocations for some previous financial years (say three years) gets statutorily incorporated. This would help the Authorization Committees to assess whether any commercial dealing is involved or not. In spite of the measures by

various state governments to curb the sale in human organs, reporting of such nefarious activities from every state continues.

In *Sadhana Bhardwaj v. The Department of Health and Family Welfare*⁹⁸⁵, approval is compulsory only at the place of the intended transplant and not at the state of domicile of the donor or recipient. Other HCs have reiterated this position as well.

In *Mukesh Gandhi v. Deputy Secretary (Health)*⁹⁸⁶, the question was with respect to procuring the organ from other states. It was held by the Gujarat HC that there is no express prohibition under the act on the procurement of organs from one state to another. The way in which authorisation or rejection for organ transplants is made has been an issue of contention. The question arises of how love and affection or special reasons are to be proven. In *Kuldeep Singh v. State of Tamil Nadu*, this question arose: Who will discharge the burden to prove love and affection? The court decided that the applicant bears this burden.

"The burden is on the applicants to establish the real intent by placing relevant materials for consideration of the Authorisation Committee. Whether there exists any affection or attachment or special reason is within the special knowledge of the applicants, and a heavy burden lies on them to establish it. Several relevant factors like a relationship, if any (need not be near relationship for which different considerations have been provided), period of acquaintance, degree of association, reciprocity of feelings, gratitude and similar human factors and bonds can throw light on the issue." This position has now been settled by the guidelines laid down in the 2014 Rules. With respect to ruling out the transplants for commercial purposes, the HCs have had different approaches. Some HCs have higher evidentiary requirements than others.

⁹⁸³ *Id.* at 373, 258 N.W.2d at 503.

⁹⁸⁴ AIR 2005 SC 2106, (2005) 11 SCC 122.

⁹⁸⁵ *Sadhana Bhardwaj v. The Department of Health and Family Welfare*, 184 (2011) DLT 150.

⁹⁸⁶ *Mukesh Gandhi v. Deputy Secretary (Health)*, AIR 2009 Guj 7.

In *Anees Ahmed v. State of U.P.*⁹⁸⁷, the requirement of an express finding with respect to the commercial nature of the transaction was laid down.

In *Poonam Gupta v. State of Punjab*⁹⁸⁸, the chances of commercial transactions were found due to the absence of the establishment of a clear relationship between the parties, and the relatives of the recipient also did not show interest in donating organs.

In *Pawan Anand v. Director General of Health Services*, the basis for the dismissal of the application to approve a transplant was the financial disparity between the donor and recipient.

Any person aggravated by the order of the AC can prefer an appeal to the State Government within 30 days of issuing the order. In *B.L. Nagaraj et al. vs Kantha et al.*⁹⁸⁹, the prospective recipient submitted an appeal in writing before the Karnataka High Court against an ordinance of the AC refusing an association donation application by the recipient's counsel on the basis that nearby family members were not called donors. In compliance with the High Court's formal request: "There is no provision in the Act that prohibits the person who is not a 'near relative' by definition from donating his kidney merely because the 'near relative' has not been considered as a donor by the family for kidney transplantation. The Committee has misdirected itself in this regard while refusing permission to the petitioners."

"The Committee would ascertain from the second petitioner whether she would be donating the kidney out of 'affection and attachment'. The donor's relationship with the recipient, period of acquaintance and the degree of association, reciprocity of feelings, gratitude and other human bonds are some of the factors that would sustain 'affection and attachment' between two individuals. The committee has to ensure that the human organ

does not become an article of commerce. The main thrust of the act is against commercial dealings in human organs." Thus, the law still has certain loopholes, which leads to confusion and opens up the scope for judicial interpretation. Such problems need to be cured to ensure that the law is specific. The basis on which the appropriate authority is to make a decision needs to be mentioned clearly to ensure uniformity. The certainty in the law will ensure that there is uniformity in the country, which will ensure equality of treatment in various circumstances. Certainty in-laws will also ensure that the process of organ transplant is fast-paced and efficacious.

CHAPTER XII

SUGGESTIONS AND CONCLUSIONS

12.1 SUGGESTIONS:

- 1) In India, brain stem death was made comparable to circulatory Death in 1994 under THOA, and the absence of brain stem reflexes along with a positive apnea test was described to certify it. However, there is no mention of ancillary tests in THOTA in India, and no national guidelines have been formed.
- 2) The performance of apnea testing might be a common problem worldwide. It is suggested that when the patient did not meet the prerequisites to perform apnea testing or had to abort apnea testing, the ancillary tests must be performed; brain death can be determined only when the ancillary tests meet the criteria for determining brain death. In addition, it is suggested that the focus of clinical determination of brain death should be focused on the optimization and technological improvement of apnea testing in order to better maintain life and organ functions and improve the performance and completion rates of apnea testing. If the clinical determination (including apnea testing) and two ancillary tests all fulfill the

⁹⁸⁷ *Anees Ahmed v. State of U.P.*, 2012 SCC OnLine All 4427

⁹⁸⁸ *Poonam Gupta v. State of Punjab*, 2009 SCC OnLine P&H 4572.

⁹⁸⁹ *B.L. Nagaraj and Ors. v. Dr. Kantha and ors.*, AIR 1996 Kant 82.

criteria of brain death, a repeat examination is not mandatory; if the clinical determination is not complete, an increased number of confirmatory tests and repeat examinations should be performed 6 h after the first examination, and there should be at least one apnea test to confirm a lack of spontaneous respiration.

- 3) Brain death has been a sensitive subject under the statute. There is a need for a consistent definition of brain death across multiple laws. There are numerous issues in cases of brain death because the individual cannot be pronounced dead under multiple definitions in various acts such as the Registration of Births and Deaths Act of 1969 and the IPC. As a result of these abnormalities, it is unclear what organs can and cannot be removed from a brain-dead person's body. When developing death criteria, the emphasis may be on WHO's 'Clinical Criteria for the Determination of Death'. It states that when developing a formula for determining death in circumstances other than Cardiac Arrest, the following elements should be considered: the basic requirements that must exist for triggering the algorithm, the clinical examination and diagnosis; and (3) confirmatory testing to ensure irreversibility.
- 4) Brain death has created a new class of dead people that does not conform to the society's expectations of normal death and dying. Brain death also causes great stress for the family and friends. Many families may benefit if a short time is provided to adjust to the sudden tragedy and hopelessness of the situation. This helps them develop trust in their physician and in the diagnosis. An effective communication with the family members, as well as caring and providing support for them is crucial

before the request for organ donation is made. The only rational reason for continuing treatment after confirming brain death is for organ donation. Once the permission from family members is obtained, the transplant team takes over further care. Law in India is still not clear if the support system can be withdrawn once the family refuses organ donation.

- 5) Once an unequivocal diagnosis of brain death has been made, most medical and legal authorities agree that continuing treatment is not in the interest of the patient or is ethically permissible. This is not related to withdrawing support to allow a patient to die, but rather to ceasing a futile intervention in a patient who is already dead. Acceptance of this approach would reduce human distress, lead to the rational use of the limited ICU facilities, and increase the availability of organs. Solid organs can be donated only after confirmation of brain death. Unless medical personnel provide family members with information that all cognitive and life support functions have irreversibly stopped, the family may harbor false hopes for the loved one's recovery.
- 6) Awareness is one of the most important tasks that must be taken. It should be noted that there is an equitable distribution of organs, and unethical acts regarding organ donations have been prohibited. India is a welfare state, and there is an immediate need to focus on infrastructure development to ensure the availability of efficient and effective health professionals, as well as the development of quality hospitals and excellent post-operative care. Here are some of the steps required for the hour. India has recognized the right to health as a basic right under Article 21. This places obligation on the state to ensure that all individuals enjoy this right.

However, because to the greater prices, many people are unable to use the hospital for organ transplants. It is important to remember that fundamental rights apply to all people, including those at the bottom of the social order. Thus, their requirements must be considered. India, as a welfare state, must spend in healthcare to establish an equitable organ transplant program. India still has to develop in this area; just a portion of the population gets health insurance. To cover the high costs of organ transplantation, health insurance plans must be created with this in mind.

12.2 CONCLUSION

Determination of brain death has been a contentious issue in India. The methods used for determination of brain death is not often disputed. But the associated procedures of organ transplantation are always called into question. The Transplantation of Human Organs Act of 1994 marked a significant advancement in the field of organ transplantation in India. Most crucially, it legalized brain-stem death, enabling cadaver donor transplants. The Act greatly regulated living donor transplants, but it made obtaining clearance difficult, even in genuine circumstances. Anyone who violates any term of the Act faces serious penalties, and unfortunately, transplant team doctors are held accountable in most situations. Changing medical technology poses new problems for our old standards of what constitutes death. Our values inevitably shape what we think of as the death of a person, and death is not merely a descriptive, scientific concept, but inescapably contains evaluative content. The changing frontiers of death force us to confront foundational questions of persons and values, hopefully in a way which will better prepare us to address future questions. It is vital that we examine the evaluative content in our concepts and practices relating to death, and reflect on what it is that we value or should value in persons. The neurological criteria for death

represent a remarkable advance in our ways of responding to changes in death and dying. However, as medical technology and life extension techniques develop, we must also develop increasingly precise notions of what aspects of our neurological lives are the most important. While the current total brain death standard currently suffices in the vast majority of cases, the standard does not fully line up with what we value in persons. Should we retain the current brain death standard despite its mismatch with our values and despite negative consequences in determining death and in organ donation. Technological advances seem as if they will inevitably make this question inescapable.

12.3 REFERENCE

12.3.1. LIST OF ABBREVIATIONS:

1. AAN – American Academy of Neurology
2. AAP – American Academy of Pediatrics
3. ABA- Auditory Brainstem Response
4. ANA – American Neurological Association
5. AMA- American Medical Association
6. CT- Computer Tomography
7. CTA- Computer Tomography Angiography
8. CNS – Central Nervous System
9. DGHS – Health Care Directorate General
10. DDR – Dead Donor Rule
11. ECG – Electrocardiogram
12. EEG- electroencephalography
13. FDC – Family Donation Conversations
14. IPC – Indian Penal Code
15. ICP – intracranial pressure
16. IDAT – Tissue Donation Awareness Course
17. MOHAN- Multi-Organ Harvesting Aid Network

18. NOTA – National Organ Transplant Act
19. NOTP – National Organ Transplantation Programme
20. NOTTO – National Organ and Tissue Transplant Organization
21. NGOs- non-governmental groups
22. NCR – National Capital Region
23. OPO- Organ Procurement Organization
24. PVS – persistent vegetative states
25. RF – reticular formation
26. SANOK – Senior available next- of- kin
27. SSCM- Society of Critical Care Medicine
28. TCD- transcranial Doppler
29. THO – Transplantation of Human Organs
30. THOA- Transplantation of Human Organs Act
31. UDDA – Uniform Determination of Death Act
32. WHO – World Health Organization

12.3.2 ACTS AND CONVENTIONS

- 1) The Uniform Determination of Death Act, 1980
- 2) Transplantation of Human Organs Act, 1994
- 3) Uniform Determination of Death Act, 1981
- 4) Uniform Brain Death Act, 1978
- 5) Model Definition of Death Act,
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