

Brain Death Criteria and Deceased Organ Donation: A Comparative Review of Legal Standards and Clinical Practice

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ABSTRACT

Brain death, increasingly referred to as death by neurologic criteria, is an established medical and legal determination of death in many jurisdictions and is particularly relevant to deceased organ donation. Despite broad agreement on the essential clinical features, including permanent unconsciousness, absence of brainstem reflexes, and absence of spontaneous breathing, considerable variation exists in legal definitions, diagnostic prerequisites, examiner qualifications, apnea-testing procedures, observation periods, and ancillary investigations. This narrative review compares contemporary clinical and legal standards for brain-death determination and examines their implications for deceased organ donation, focusing on the United States, United Kingdom, Canada, India, and Australia/New Zealand. Relevant peer-reviewed literature, international consensus statements, professional guidelines, and statutory documents published between 1968 and September 2026 were reviewed, with particular attention to major international and national guidelines. Contemporary standards consistently require an established catastrophic brain injury, exclusion of reversible confounding factors, demonstration of unresponsiveness and absent brainstem reflexes, and formal assessment of apnea. However, important jurisdictional differences persist. The United States predominantly applies a whole-brain legal formulation, whereas the United Kingdom follows a brainstem-based clinical approach. Canada has adopted a unified brain-based definition of death, while India legally recognizes brainstem death within its transplantation framework. Additional differences concern repeat examinations, examiner requirements, and the indications for ancillary testing. These variations may affect diagnostic consistency, clinical training, family communication, and deceased organ donation practices. Greater international harmonization of terminology, diagnostic prerequisites, clinical examination procedures, documentation, and ancillary-testing standards may improve consistency and public confidence. Nevertheless, harmonization must respect national legal frameworks, and determination of death must remain clinically and ethically independent of transplant eligibility and authorization for organ donation.

Keywords: Brain death; Death by neurologic criteria; Brainstem death; Deceased organ donation; Clinical guidelines; Legal frameworks; International harmonization.

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INTRODUCTION

Advances in mechanical ventilation, cardiopulmonary resuscitation, neurocritical care, and intensive care medicine fundamentally altered the traditional relationship between cessation of cardiac activity and human death. Mechanical ventilation can maintain oxygenation, circulation, organ perfusion, and many somatic functions despite catastrophic and permanent loss of neurologic function. These developments created the need for diagnostic criteria capable of recognizing death in mechanically ventilated patients whose hearts continue to beat. The 1968 report of the Ad Hoc Committee of Harvard Medical School represented a landmark in this development by proposing criteria for what was then described as “irreversible coma.”^[1] Subsequent clinical, philosophical, and legal work progressively established brain death as a recognized means of determining human death.^[2]

Brain death should not be equated with severe coma, vegetative state/unresponsive wakefulness syndrome, or minimally conscious state. In these conditions, some neurologic functions remain, and the individual is alive. Brain death, or death by neurologic criteria (BD/DNC), requires permanent loss of the neurologic functions specified by the applicable medical and legal standard. The clinical diagnosis generally involves three cardinal findings: Coma or complete unresponsiveness, absence of relevant brainstem reflexes, and absence of spontaneous breathing despite an adequate hypercarbic stimulus.^[2,3]

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Despite widespread acceptance, however, no completely uniform international standard has historically existed. Earlier global comparisons demonstrated marked variation in temperature thresholds, observation periods, qualifications and numbers of examining physicians, apnea-test procedures, and requirements for confirmatory investigations.^[3] A more recent

international evaluation similarly demonstrated substantial heterogeneity among national protocols even though most shared common fundamental clinical principles.^[4]

Efforts to reduce these variations culminated in the World Brain Death Project, which proposed internationally applicable minimum clinical standards for determining BD/DNC.^[5] The project emphasized that BD/DNC is fundamentally a clinical diagnosis. A patient must have an established catastrophic and permanent brain injury capable of causing the condition, reversible confounders must be excluded, and examination must demonstrate coma, absence of brainstem reflexes, and apnea. Ancillary testing is required only when the clinical assessment cannot be safely completed or reliably interpreted.^[5]

Nevertheless, legal formulations remain different. In the United States (US), DNC has traditionally been expressed through a “whole-brain” model based on irreversible cessation of all functions of the entire brain, including the brainstem.^[6,7] The United Kingdom (UK) has historically employed a brainstem-oriented formulation and now follows the Academy of Medical Royal Colleges’ 2025 Code of Practice, the first major update of its national guidance since 2008.^[8] Canada published an extensively revised guideline in 2023 defining death through the permanent cessation of brain function.^[9] India defines “brain-stem death” statutorily through the Transplantation of Human Organs and Tissues Act (THOTA), with detailed certification requirements specified in national rules.^[10,11] Australia and New Zealand use the Australian and New Zealand Intensive Care Society (ANZICS) professional standard, although specific legal provisions vary between jurisdictions.^[12]

These variations become especially important in the setting of organ transplantation. Deceased organ donation following neurologic determination of death enables maintenance of circulation until organ retrieval, thereby limiting warm ischemic injury and permitting transplantation of multiple organs. Yet the association between brain death and organ donation can also generate misunderstanding. Brain death is not a diagnosis made for the purpose of obtaining organs. Determination of death is a medical and legal process that must be undertaken independently of whether a patient is medically suitable for donation or whether donation will subsequently be authorized.

The objectives of this narrative review are therefore to describe the contemporary clinical criteria for BD/DNC, compare major international legal and professional standards, examine the relationship between neurologic determination of death and deceased organ donation, identify ethical and operational controversies, and propose priorities for improving consistency, transparency, and public confidence.

METHODOLOGY

A focused narrative literature review was undertaken to identify contemporary clinical, legal, ethical, and transplantation-related evidence concerning BD/DNC. Peer-reviewed publications were identified principally through biomedical literature databases and reference tracing, supplemented by authoritative professional guidelines, national legislation, governmental documents, and major international consensus statements.

Search concepts included combinations of “brain death,” “death by neurologic criteria,” “brain-stem death,” “neurological determination of death,” “apnea testing,” “ancillary testing,” “deceased organ donation,” “organ transplantation,” “brain death legislation,” “legal definition of death,” “whole-brain death,” and “brainstem death.”

The review covered literature from 1968, when the Harvard criteria were published, through September 2026. Priority was given to documents with direct relevance to contemporary practice, particularly the World Brain Death Project,^[5] the 2023 American Academy of Neurology/American Academy of Pediatrics/Child Neurology Society/Society of Critical Care Medicine consensus guideline,^[6] the 2023 Canadian guideline,^[9] the Academy of Medical Royal Colleges’ 2025 UK Code of Practice,^[8] the ANZICS Statement on Death and Organ Donation,^[12] and Indian statutory provisions.^[10,11]

The review was narrative rather than systematic; therefore, quantitative meta-analysis and formal risk-of-bias assessment were not undertaken. Legal comparisons were restricted to broad principles relevant to clinical practice and should not substitute for jurisdiction-specific legal advice.

CONCEPTUAL BASIS AND TERMINOLOGY

BD/DNC

The term “brain death” remains widely used in clinical practice and legislation. Increasingly, professional organizations use DNC or BD/DNC. The latter terminology emphasizes that there are not two different types of death. Rather, death may be determined by neurologic or circulatory criteria depending on the clinical circumstances.^[5,13]

The concept is functional rather than histological. It does not require proof that every neuron has undergone structural destruction. Instead, clinicians determine that the neurologic functions required under the applicable definition of death have permanently or irreversibly ceased.

Whole-brain and Brainstem Formulations

A major conceptual difference between jurisdictions involves whether the legal or clinical standard is expressed as cessation of functions of the entire brain or of functions mediated principally through the brainstem.

The whole-brain approach is associated particularly with the US. The Uniform Determination of Death framework describes death as either irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the entire brain, including the brainstem.^[7]

The UK’s approach instead focuses on permanent loss of the capacity for consciousness and permanent loss of the capacity to breathe, established clinically through permanent loss of brainstem function.^[8] Despite different conceptual language, there is substantial overlap in the actual bedside neurological examinations performed.

India explicitly uses the statutory expression “brain-stem death,” defined as the stage at which all functions of the brainstem have permanently and irreversibly ceased and have been certified according to the prescribed procedure.^[10]

CLINICAL DETERMINATION OF BRAIN DEATH

Determination of BD/DNC is primarily clinical. Testing should begin only after appropriate prerequisites have been fulfilled. The World Brain Death Project and subsequent national guidelines have strengthened the emphasis on avoiding false-positive determination caused by reversible conditions.^[5,6] Table 1 shows

the Core components of the clinical determination of brain death/death by neurologic criteria

Establishing the Cause of Catastrophic Brain Injury

A known and sufficient cause of catastrophic brain injury must be established. Common etiologies include severe traumatic brain injury, massive intracranial hemorrhage, aneurysmal subarachnoid hemorrhage, extensive ischemic stroke, hypoxic-ischemic brain injury, malignant cerebral edema, and certain fulminant intracranial infections.

Clinical history and neuroimaging should be consistent with the severity and distribution of injury expected to cause permanent loss of brain function. If the apparent neurological examination cannot be explained by an identified catastrophic brain lesion, BD/DNC should not be declared, and further diagnostic investigation is required.^[5,6]

Exclusion of Confounding Factors

Potentially reversible conditions capable of suppressing neurologic responses must be excluded. Important confounders include hypothermia, hypotension, severe electrolyte abnormalities, major acid-base or endocrine disturbances, sedative or anesthetic agents, intoxication, residual neuromuscular blockade, and selected severe neuromuscular disorders.

The 2023 US consensus guideline requires a core temperature of at least 36°C before evaluation and introduced a conservative approach after significant hypothermia. Medication clearance should account for drug half-life, dose, renal and hepatic function, body composition, and temperature; longer observation may be necessary when metabolism is impaired.^[6]

Hemodynamic stability is likewise essential because profound hypotension can suppress cerebral function and make testing unsafe. Adequate blood pressure should therefore be maintained with fluids, vasopressors, or inotropic support when necessary.

Neurological Examination

After prerequisites have been satisfied, clinical assessment establishes the absence of consciousness and brainstem-mediated responses. Core components generally include:

- Absence of purposeful or brain-mediated response to appropriate stimulation
- Absence of pupillary response to light
- Absence of corneal reflexes
- Absence of oculcephalic responses when testing is safe
- Absence of oculovestibular responses
- Absence of facial movement following appropriate stimulation
- Absence of gag and cough reflexes; and
- Absence of spontaneous respiratory effort during an appropriately conducted apnea test.

Spinally mediated movements may occasionally remain after brain death and must be distinguished from movements generated by the brain or brainstem.^[5,6] Their presence, when clearly spinal in origin, does not invalidate the diagnosis.

Apnea Testing

The apnea test evaluates whether the medullary respiratory centers respond to an adequate hypercarbic and acidemic

stimulus. It represents one of the most important components of BD/DNC determination but is also one of the elements displaying the greatest international procedural variation.^[4,5]

Before testing, the patient should be hemodynamically stable, adequately oxygenated, and appropriately ventilated. Baseline arterial blood gas assessment is required. Oxygenation is maintained while carbon dioxide is allowed to rise under controlled conditions.

Under the 2023 US guideline, in patients without chronic carbon dioxide retention, the arterial PaCO₂ should ordinarily be within the normal range before testing. A result consistent with BD/DNC requires absence of spontaneous respiratory effort together with an arterial pH below 7.30 and PaCO₂ of at least 60 mmHg and at least 20 mmHg above the pre-apnea baseline.^[6] Special considerations apply when chronic hypercarbia is known or suspected.

The procedure must be interrupted when significant hypoxemia, hypotension, or unstable cardiac arrhythmia develops. If apnea testing cannot be safely completed, an accepted ancillary investigation may be required according to jurisdictional guidance.

Ancillary Investigations

Ancillary investigations should not substitute automatically for a competent clinical examination. They are principally indicated when one or more required components of the neurological examination or apnea test cannot be completed or reliably interpreted.

Common categories include cerebral blood-flow/perfusion tests and, in some jurisdictions, electrophysiological studies. Importantly, accepted modalities are not identical internationally.

The 2023 US consensus guideline recognizes four-vessel catheter angiography, radionuclide cerebral perfusion imaging, and transcranial Doppler ultrasonography in adults as acceptable ancillary methods. The updated US guideline does not recommend electroencephalography, computed tomography angiography, magnetic resonance imaging, or magnetic resonance angiography as ancillary tests for BD/DNC.^[6] This is an important change from older American practices.

Other jurisdictions permit different imaging techniques. Consequently, a test considered adequate in one country cannot automatically be assumed to satisfy another jurisdiction's legal or professional standard.

COMPARISON OF MAJOR LEGAL AND CLINICAL STANDARDS

US

In the US, the dominant legal model derives from the Uniform Determination of Death Act, under which death can be established by irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the entire brain, including the brainstem.^[7]

Clinical practice is now guided principally by the 2023 multidisciplinary consensus guideline.^[6] Adults require a minimum of one clinical examination; a second independent examination may be performed. Pediatric patients require two independent examinations, separated by at least 12 h, and two apnea tests – one associated with each examination.^[6]

The exact legal implementation nevertheless remains subject to state law and institutional policy.

UK

The UK employs a neurological standard centered on permanent loss of the capacity for consciousness and the capacity to breathe as a consequence of permanent loss of brainstem function. The 2025 Academy of Medical Royal Colleges Code of Practice represents the current national professional standard and applies across age groups, with age-specific safeguards.^[8] It was the first major revision of the UK Code since 2008.

Neurological determination requires appropriately experienced medical practitioners, with two doctors involved and two complete sets of clinical testing. Specific additional precautions apply in young children. The diagnosis of death remains independent of the decision regarding organ donation.

Canada

Canada published a major national clinical practice guideline in 2023 that proposed a unified brain-based definition of death based on permanent cessation of brain function.^[9] The guideline applies neurological determination of death to mechanically ventilated patients regardless of their potential for organ donation.

The Canadian guideline particularly emphasizes established catastrophic brain injury, exclusion of confounding conditions, neuroimaging where appropriate, and standardized neurological and apnea testing. Canadian law nevertheless remains partly provincial or territorial, creating some continuing jurisdictional variation.

The related Canadian legal and ethical analysis concluded that substantial authority supports the position that separate consent is generally not required merely to determine whether death has occurred, although clinicians should notify families and reasonable temporary accommodation may be appropriate in selected cases.^[14]

India

India formally recognizes brain-stem death under the THOTA, 1994, subsequently amended.^[10] The Act defines brain-stem death as permanent and irreversible cessation of all functions of the brainstem certified in the prescribed manner.

Where organs or tissues are to be retrieved after brain-stem death, certification is undertaken by a statutory board consisting of specified medical professionals. Ordinarily, these include the registered medical practitioner in charge of the hospital, an independent approved specialist, a neurologist or neurosurgeon, and the treating registered medical practitioner. Statutory substitution provisions exist when a neurologist or neurosurgeon is unavailable.^[10]

Form 10 of the Transplantation of Human Organs and Tissues Rules, 2014 documents the required examination. It includes assessment of coma, pupillary responses, brainstem reflexes, motor responses, gag and cough responses, caloric testing, and apnea testing. The patient is examined twice; for adults, the minimum interval between the two examinations is 6 h.^[11]

Indian literature has repeatedly emphasized the need for clinician education, standardized certification, and distinction between the medical diagnosis of brain-stem death and the subsequent decision regarding organ donation.^[15-17]

Australia and New Zealand

The ANZICS Statement on Death and Organ Donation provides a major professional standard for Australia and New Zealand.^[12] It

recommends neurological determination by two doctors, at least one of whom should be a specialist, each independently determining death in accordance with the statement and jurisdictional legislation. ANZICS also explicitly states that neurological determination should occur when indicated regardless of whether organ donation is being contemplated.^[12]

The comparison demonstrates that a patient may undergo somewhat different procedural requirements depending on jurisdiction even though the underlying clinical syndrome being identified is highly similar. [Table 2] Comparative overview of selected international standards for neurologic determination of death.

BRAIN DEATH AND DECEASED ORGAN DONATION

Relationship between Death Determination and Donation

Neurological determination of death has major practical importance for transplantation because mechanical ventilation and cardiovascular support may continue after death has been established. This allows oxygenated blood to continue circulating through transplantable organs until retrieval.

However, clinical determination of death and organ donation is separate processes. A patient's suitability or willingness to donate organs does not determine whether the patient satisfies neurological criteria for death. The same clinical standard should apply whether organ donation is possible, impossible, accepted, or declined.

This separation is fundamental to professional integrity and public confidence. Clinicians involved in organ recovery should not exert influence over whether death is declared. The 2023 US guideline specifically requires avoidance of conflicts of interest in determination of BD/DNC,^[6] while ANZICS explicitly states that neurological death should be determined regardless of donation status.^[12]

Donation after Neurologic Determination of Death

Donation after brain death, also described as donation after neurologic determination of death, traditionally constitutes a major source of transplanted hearts, lungs, livers, kidneys, pancreata, and intestines. Physiological support can preserve organ perfusion while consent, donor evaluation, allocation, surgical planning, and retrieval are undertaken.

Current global data demonstrate the continuing importance of deceased donation. The Global Observatory on Donation and Transplantation reported a record 173,727 solid-organ transplants worldwide in 2024, while 47,180 actual deceased donors were reported. Donation after circulatory determination of death accounted for approximately 28% of deceased donation activity; neurologically determined death therefore continued to represent the larger deceased-donor pathway internationally.^[18]

Donation Authorization is Separate from Death Certification

Declaration of brain death does not itself authorize removal of organs. Donation requires a separate legal authorization or consent process

in accordance with the relevant jurisdiction's donation system, including consideration of donor registration, prior expressed wishes, family or surrogate authority, and statutory requirements.

In India, for example, Form 10 concerns certification of brain-stem death, whereas declaration/consent for donation is addressed separately within the THOTA framework.^[10,11] This distinction should be made explicit to families to prevent the misconception that testing for brain death is being undertaken primarily to facilitate transplantation.

DONOR MANAGEMENT AFTER NEUROLOGIC DETERMINATION OF DEATH

Once death has been legally established and organ donation has been authorized, physiological support may continue temporarily for the purpose of maintaining organ viability. Brain death may produce profound cardiovascular, endocrine, inflammatory, thermoregulatory, pulmonary, and metabolic disturbances.

Management may therefore require mechanical ventilation, vasopressor or inotropic support, fluid and electrolyte optimization, temperature control, treatment of diabetes insipidus, correction of glucose abnormalities, and organ-specific evaluation. These interventions do not constitute treatment intended to reverse the donor's death. Rather, they are directed toward preserving transplantable organ function after death has already been determined.

Clear documentation of the legally recognized time of death is essential. Continued circulation produced by ventilation and pharmacological support does not alter the determination once neurologic criteria have been validly fulfilled.

ETHICAL ISSUES

The Dead-donor Rule

A central ethical principle in deceased organ transplantation is the dead-donor rule: vital organs should be removed only from individuals who have been determined dead, and organ procurement itself should not be the cause of death.^[19]

Brain-death determination allows organ retrieval before circulatory collapse while respecting this principle. Nevertheless, philosophical debate has continued over what biological functions are necessary for an organism to be considered dead and whether the whole-brain concept adequately captures this boundary.^[19,20]

These debates should not be confused with the clinical question of whether an individual satisfies a legally accepted standard of death. Clinicians are required to work according to established professional standards and applicable law while acknowledging that the philosophical foundation of death remains an area of scholarly discussion.

Residual Biological Activity

Some patients meeting accepted criteria for brain death may retain spinal reflexes, hormonal activity, wound healing, cardiovascular responsiveness, or other cellular and organ functions. Such observations have historically generated conceptual debate.^[20]

Brain death, however, does not signify the simultaneous death of every cell or organ. Contemporary criteria assess the permanent absence of neurologic functions specified by the

applicable standard. Spinally mediated movement therefore does not necessarily imply persistence of brain function.

Consent for Brain-death Testing

Whether explicit surrogate consent is required before testing varies according to jurisdiction. In many systems, determination of death is viewed as part of a clinician's professional obligation rather than an elective procedure requiring surrogate authorization.

Canadian legal and ethical analysis, for example, identified substantial authority supporting determination without separate consent while simultaneously emphasizing advance notification, compassionate communication, and reasonable accommodation when practicable.^[14] This approach should not automatically be extrapolated to every jurisdiction because legislation and case law differ. [Table 3] Major areas of variation and their potential clinical consequences.

Religious, Cultural, and Family Concerns

Families may find neurological death particularly difficult to understand because the patient's chest continues to move with mechanical ventilation, the skin may remain warm, a pulse is palpable, and cardiovascular monitors continue to display activity. These features may appear inconsistent with everyday understandings of death.

Religious and cultural traditions also differ in their interpretation of neurological criteria. Respectful communication should therefore include an explanation of what has happened to the brain, what clinical tests demonstrate, why the condition cannot recover, and why mechanical ventilation can temporarily preserve circulation despite death.

Where legally and clinically feasible, short-term accommodation may allow families time to understand the diagnosis, gather relatives, consult spiritual advisers, or complete culturally important rituals. Accommodation, however, should not require clinicians to misrepresent the patient's legal status or alter established diagnostic standards.

COMMUNICATION WITH FAMILIES

Communication is not ancillary to brain-death determination; it is an important component of ethically sound clinical practice.

Clinicians should begin discussing the severity and prognosis of catastrophic brain injury before formal testing whenever clinically appropriate. Families should understand that testing is being undertaken because the clinical findings raise concern that death may already have occurred, not because the healthcare team has decided to discontinue treatment or obtain organs.

Once death is confirmed, terminology should be unambiguous. Expressions such as "almost dead," "brain dead but still alive," or "only legally dead" may unintentionally reinforce misunderstanding. The clinician should explain that the individual has died and that the ventilator is mechanically moving air into and out of the lungs.

Discussion of organ donation should be coordinated according to local legal requirements and donation-service protocols. Separation of the determination-of-death process from the request for donation helps reduce perceived conflicts of interest and strengthens trust.

Table 1: Core components of the clinical determination of brain death/death by neurologic criteria

<i>Component</i>	<i>Essential requirement</i>	<i>Major considerations</i>
Established cause	Catastrophic and permanent brain injury capable of producing BD/DNC	Clinical history and neuroimaging should be compatible
Consciousness	Complete absence of consciousness and brain-mediated responsiveness	Spinal reflexes may persist
Pupillary response	No pupillary response to bright light	Exclude ocular trauma/drug effects
Corneal reflex	Absent bilaterally	Adequate stimulation required
Oculocephalic reflex	Absent when cervical-spine integrity permits testing	Avoid if cervical injury suspected
Oculovestibular reflex	No eye movement after appropriate caloric stimulation	Tympanic membrane/external ear considerations apply
Facial motor response	No brain-mediated facial response to stimulation	Facial trauma may interfere
Gag/cough	Both absent	Test appropriate cranial nerve pathways
Apnea	No spontaneous respiratory effort despite an adequate CO ₂ /pH stimulus	Oxygenation and hemodynamic stability essential
Confounders	Reversible causes excluded	Hypothermia, drugs, paralysis, metabolic/endocrine disturbances
Ancillary investigation	Used when required elements cannot be safely completed or interpreted	Modality depends on jurisdiction

BD/DNC: Brain death/death by neurologic criteria

Table 2: Comparative overview of selected international standards for neurologic determination of death

<i>Jurisdiction</i>	<i>Predominant conceptual/legal formulation</i>	<i>Examination requirements</i>	<i>Repeat testing</i>	<i>Ancillary testing</i>	<i>Important feature</i>
United States	Whole-brain model: irreversible cessation of all functions of entire brain, including brainstem	2023 multidisciplinary BD/DNC guideline	Minimum 1 adult examination; 2 independent pediatric examinations ≥12 h apart	Restricted to specified validated modalities when clinically required	Adult and pediatric guidance integrated in 2023
United Kingdom	Permanent loss of capacities for consciousness and breathing due to permanent loss of brainstem function	Two appropriately qualified doctors	Two complete sets of clinical tests; special pediatric safeguards	Used where clinical diagnosis cannot be completed according to Code	Current national Code updated in 2025
Canada	Brain-based definition based on permanent cessation of brain function	Standardized clinical DNC evaluation	Governed by current guideline and relevant jurisdictional requirements	Permitted when clinical criteria cannot be fully established	2023 guideline seeks unified national biomedical definition
India	Statutory “brain-stem death”	Statutory medical board	Two examinations; minimum 6-h interval in adults under Form 10	Not routinely mandatory when full clinical criteria are met	Certification embedded in THOTA framework
Australia/New Zealand	Neurological determination of death; legal wording jurisdiction-specific	Two independent doctors, one preferably specialist	Observation/waiting requirements specified by ANZICS	Cerebral perfusion testing where required	Determination should occur independently of donation consideration

THOTA: Transplantation of human organs and tissues act, BD/DNC: Brain death/death by neurologic criteria, DNC: death by neurologic criteria, ANZICS: Australian and New Zealand Intensive Care Society

Table 3: Major areas of variation and their potential clinical consequences

<i>Area of variation</i>	<i>Examples</i>	<i>Potential consequence</i>
Definition of neurologic death	Whole-brain versus brainstem versus unified brain-based formulations	Public/legal confusion across jurisdictions
Examiner requirements	One versus two or more clinicians; specialty requirements	Different thresholds for procedural confirmation
Number of examinations	Single versus repeated examination	Variable time to declaration
Observation intervals	None prescribed to several hours or longer	Delayed declaration and donor management
Temperature thresholds	Different historical thresholds	Risk of premature testing if protocols outdated
Drug exclusion	Variable waiting periods and pharmacokinetic approaches	Potential confounding from sedatives
Apnea-test endpoints	Variation in PaCO ₂ , pH and duration requirements	Inconsistent test interpretation
Ancillary tests	Differences in acceptance of EEG, angiography, radionuclide imaging, TCD or computed tomography-based techniques	A test accepted in one jurisdiction may be invalid in another
Pediatric standards	Different observation and examination requirements	Greater complexity in children
Consent/accommodation	Different statutory and case-law approaches	Conflict between clinicians and surrogates
Relationship to transplant law	Death law independent versus transplantation-linked statutory framework	Different administrative and certification processes

EEG: Electroencephalography, TCD: Transcranial Doppler

Public attitudes toward brain death and transplantation remain influenced by the way clinicians and institutions explain these concepts, reinforcing the need for high-quality communication and public education.^[21]

MAJOR SOURCES OF INTERNATIONAL VARIATION

Despite substantial convergence in broad principles, several areas remain inconsistent.

A global evaluation of official protocols demonstrated substantial variation in these domains, supporting continuing efforts toward international minimum standards.^[4]

CHALLENGES IN THE INDIAN CONTEXT

The Indian framework deserves particular attention because brain-stem death is explicitly recognized within transplantation legislation. THOTA provided an essential legal foundation for deceased organ donation and transplantation; nevertheless, several implementation challenges have historically persisted.^[10,11,15-17]

First, clinicians outside major transplant and neurocritical-care centres may have limited practical exposure to brain-stem-death certification. Lack of confidence in performing brainstem reflex testing or apnea testing may delay recognition and certification.

Second, statutory requirements involving multiple certifying physicians can create logistical barriers, particularly in hospitals with limited neurological or neurosurgical expertise. Amendments permitting alternatives when neurologists or neurosurgeons are unavailable were intended to improve feasibility.^[10]

Third, linking statutory brain-stem-death certification closely with organ transplantation can unintentionally create the public impression that the diagnosis exists primarily to facilitate donation. Conceptually, determination of death should remain independent of transplantation. The possibility of organ donation should arise only after or alongside a clinically appropriate and legally valid death-determination pathway, without modifying diagnostic criteria.

Fourth, public awareness remains important. Families may be unfamiliar with brain-stem death or may interpret continuing heartbeat and ventilator-generated chest movement as evidence of ongoing life. Standardized counseling by trained critical-care clinicians and transplant coordinators can reduce misunderstanding.

Finally, nationwide training, audit, and standardized documentation could improve consistency between institutions and states.

TOWARD INTERNATIONAL HARMONIZATION

Absolute international uniformity may be unrealistic because definitions of death exist within different constitutional, statutory, cultural, and religious frameworks. Nevertheless, the core medical procedure can be harmonized substantially.

The World Brain Death Project provides a valuable minimum framework.^[5] Priority areas include establishing a known catastrophic brain injury; applying conservative prerequisites; standardized exclusion of drugs, hypothermia, and metabolic confounders; complete brainstem examination; standardized apnea testing; clearly defined indications for ancillary investigation; competency-based clinician training; and structured documentation.

Updated institutional policies are also essential. Continuing use of older protocols may lead to inconsistent temperature thresholds, outdated apnea endpoints, or use of ancillary studies no longer supported by current national guidance. For example, the change in the 2023 US recommendations regarding acceptable ancillary tests illustrates why local policies require periodic revision.^[6]

A second priority is separating determination of death from organ donation. The clinical criteria should be identical regardless of donation potential. Donation teams may become involved after appropriate referral, but transplantation interests should never influence whether the diagnostic criteria for death are fulfilled.

A third priority is communication. Harmonized terminology such as “death by neurologic criteria” may help explain that neurological and circulatory criteria represent different ways of determining the same outcome – death – rather than different degrees or types of death.

FUTURE DIRECTIONS

Future work should address both scientific and implementation gaps. Prospective studies are needed to evaluate the diagnostic accuracy and reproducibility of emerging cerebral-perfusion imaging techniques under clearly defined conditions. Research should also investigate apnea testing during extracorporeal membrane oxygenation and other technologically complex forms of cardiopulmonary support.

International organizations and professional societies should continue working toward agreed minimum standards while allowing countries to retain legally required additional safeguards. Competency-based simulation and standardized certification programs could reduce variation between individual clinicians.

Lower-resource settings require particular attention because ancillary cerebral blood-flow investigations, trained specialists, and advanced neuroimaging may be unavailable. Standards should therefore remain clinically rigorous while avoiding unnecessary technological requirements when a complete bedside diagnosis can be safely established.

Finally, additional empirical research is required regarding public understanding, family experiences, religious concerns, and the most effective methods of communicating neurological death.^[21] These domains are directly relevant to public confidence in both critical care and organ transplantation.

CONCLUSION

BD/DNC is a medically established means of determining human death in a patient with catastrophic and permanent brain injury who has lost the neurologic functions required by the applicable clinical and legal standard. Although international protocols share the essential elements of established catastrophic brain injury, exclusion of reversible confounders, coma, absence of brainstem reflexes, and apnea, important differences persist in legal definitions, examiner requirements, observation periods, apnea-testing thresholds, pediatric procedures, and ancillary investigations.

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