

# Conceptual Controversies in ICU Death Determination

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# Disclosures

- No financial interests
- Relevant National/International Committees
  - *DHHS HRSA Panel on Determining Circulatory Death (Chair)*
  - *WHO Committee on Criteria for the Determination of Death (Meetings #1 and 2 but not #3)*

# Objectives

- Brain determination of death:
  - Show how the validity of “brain death” depend on the concept of cessation of the organism as a whole
- Circulatory-respiratory determination of death:
  - Explain the noncongruence between the biological concept of death and the medical determination of death
  - Show the relevance of distinguishing the *permanent* and *irreversible* cessation of circulatory-respiratory functions
- Dead donor rule:
  - Contrast the impact of maintaining vs. abandoning it

# ICU Death Determination

- Clarity spurred by organ donation programs but must remain coherent independently
- Brain determination of death (DBDD)
- Circulatory determination of death (DCDD):
  - “Non-heart-beating organ donation”
  - “Donation after cardiac death”
- More active controversies now involve death determination in DCDD than DBDD

# Approaches to Death Determination

- Biological-Ontological
  - Because death is irreversible by definition, it requires the *irreversible* cessation of functions
- Legal
  - Statutes stipulate the *irreversible* cessation of functions but defer to medical standards
- Medical practice
  - Traditionally requires showing the *permanent* cessation of circulatory and respiratory functions

# Legal Definition of Death in USA

## *Uniform Determination of Death Act (UDDA):*

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

President's Commission. *Defining Death*, 1981

# Brain-Circulation Relationship

- The neurological criterion is the fundamental criterion of death: “brain death”
- The circulatory-respiratory criterion of death is valid because, in the absence of CPR, it leads to fulfilling the brain criterion
- Only in the presence of respiratory-circulatory support is the brain criterion tested

Bernat JL et al. *Ann Intern Med* 1981;94:389-394

# “Brain Death”

- Irreversible cessation of all brain clinical function constitutes human death
- Misleading but standard term
- Accepted by physicians and society though persisting confusion about definitions
- Accepted better by physicians than families; opposite of circulatory death which is accepted better by families than physicians



# “Brain Death” Internationally

- Law in all states in the USA and throughout the developed and developing world
- Practiced in more than 80 countries with varying legality and test requirements
- Critiques for over 40 years have not gained traction with the public:
  - No laws changed in any jurisdiction
  - No practices changed by medical societies

# “Brain Death” Intuitive Acceptance

- Surveys show widespread misunderstanding of definitions but conceptual acceptance
- Academic disputes persist but critics for over 40 years have not succeeded in changing laws anywhere or practices recommended by medical societies
- Recent survey: medical professionals say it is more reliable than circulatory death

# Analysis of Death

- Sequential analysis: proceeds from the conceptual to the measurable
  - **Paradigm**: preconditions that frame analysis
  - **Definition**: make explicit ordinary meaning when we use the word *death*
  - **Criterion**: general measurable standard
  - **Tests**: physicians devise and perform
- Even opponents concur with analysis format

# Death: Definition & Criterion

- **Definition:** irreversible cessation of the critical functions of the organism as a whole
- **Criterion:** irreversible cessation of function of a critical number of neurons of the cerebral hemispheres and brain stem (“whole-brain formulation”)
- **Tests:** adults: AAN 2010, children: multisociety task force, 2011

# Whole-Brain Criterion of Death

- Determination requires the irreversible cessation of whole-brain function
- Higher brain formulation is popular in academic circles but is not accepted anywhere in the world
- Brain stem criterion accepted in UK
- Requires cessation of clinical functions, not all neuronal activities

# Whole-Brain Criterion Features

- Increased intracranial pressure:
  - Transtentorial brain herniation
  - Loss of intracranial blood flow
  - Secondary diffuse neuronal death
- Fail-safe mechanism to assure loss of all brain clinical functions
- Ancillary tests: no intracranial blood flow

# Attacks Leading to Refinements

- Choice of the definition of death
- Imprecise correspondence between the definition and criterion of death
- Perceived inadequacies of the advocated whole-brain criterion of death
- The impossibility of stating any uniform definition of death

# “Brain Death” Critiques

- Shewmon: not what we mean by *death*; integration occurs outside the brain;
- Veatch: “higher brain formulation”
- Truog: an unnecessary anachronism
- Taylor: a legal fiction to permit organ donation
- McMahan, Lizza: more than one kind of death
- Chiong: no uniform definition of death



# Alan Shewmon Critique

- The inadequacy of the integration rationale for the whole-brain criterion was endorsed by the US President's Council on Bioethics
- Shewmon criticized the Council's alternative rationale "the inability of the organism to conduct its self-preserving work" as having the same flaw as that which they replaced
- Need greater refinement about the organism as a whole to defend whole-brain criterion

# Organism as a Whole

- Not whole organism
- Greater than the sum of component parts
- Organism's unity, wholeness, integrity
- Life of cell, tissue, organ or other component part differ from life of organism (as a whole)
- Brain dead patient is dead but subsystems remain alive with technological support
- Emergent functions of whole organism

Loeb J. *The Organism as a Whole*. G.P. Putnam's Sons, 1916

# Emergent Functions

- Function of a whole entity that is not present in any of its component parts
- Emerge spontaneously from naturally occurring ensembles of cells, tissues, and organs
- Cannot be predicted or understood by studying component subunits
- Human conscious awareness is the most exquisite example: an ineffable emergent function of the ensemble of distributed parallel hierarchical networks of brain neurons

Mahner M, Bunge, M. *Foundations of Biophilosophy*. Springer-Verlag, 1997

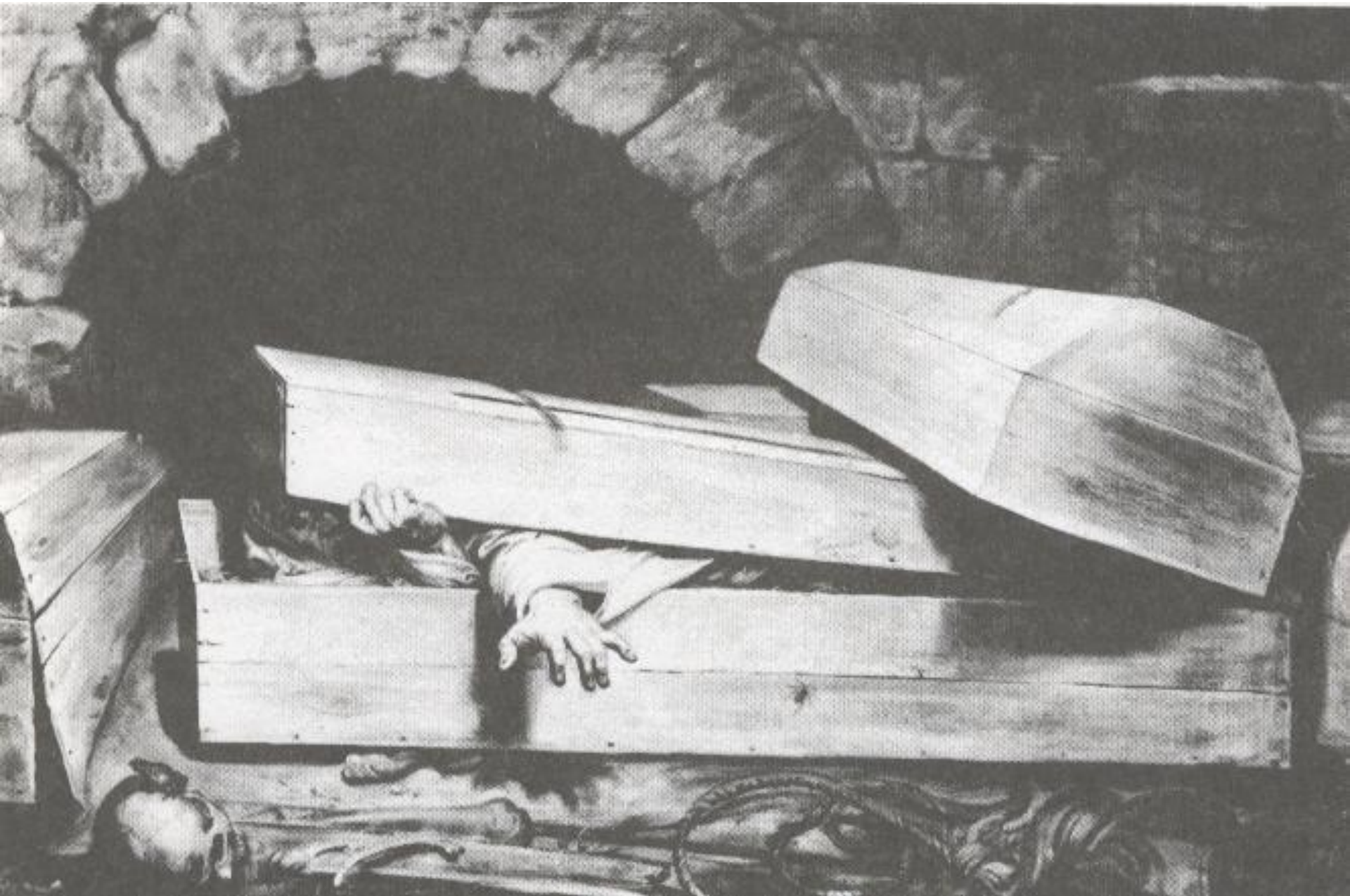
# Why Brain Death is Human Death

- The brain dead patient is dead because of the cessation of functioning of the organism as a whole: the loss of critical emergent functions
- Parts of the organism (organ subsystems) remain alive with technological support
- Principles of biological mereology: the study of the relationship between a whole organism and its parts

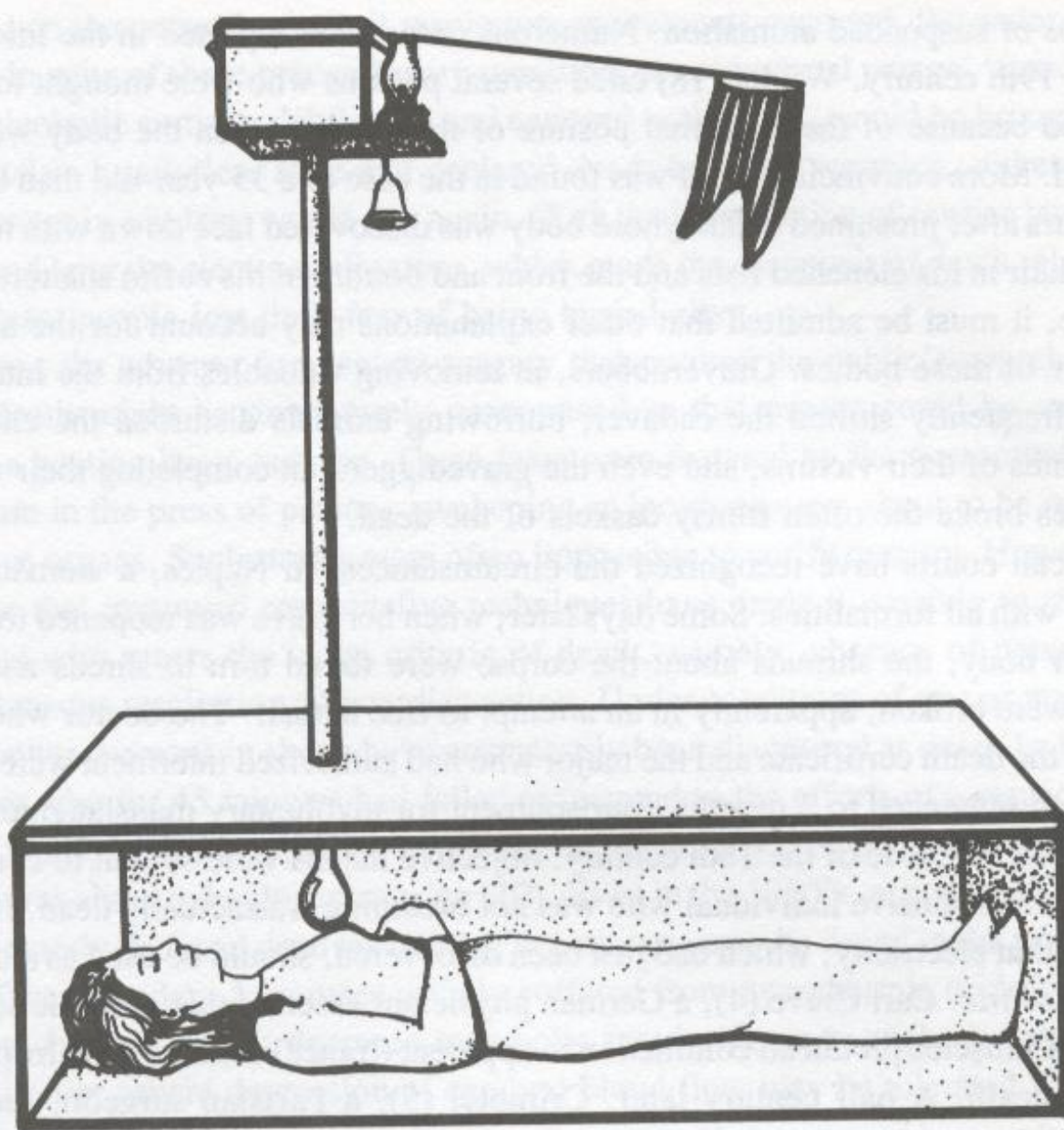
Huang AP, Bernat JL. (submitted manuscript)

# Tests of Death

- Cardiopulmonary tests are adequate in cases without ventilatory support
- Brain death tests must be used when ventilatory support is used or planned
- Tests must have no false-positive determinations and as few false-negatives as possible



Antoine Wiertz (1806-1865) *L'inhumation précipitée* Wiertz Museum, Brussels



I-2 A device patented by Count Karnice-Karnicki to assure that, if prematurely buried, a person could make known his or her living state.

# Brain Death: Examination

- Known structural lesion that accounts for clinical findings
- Exclude all reversible causes
- Unresponsiveness to all stimuli
- Cranial nerve areflexia
- Apnea, tested properly (respiratory therapy protocol)

Wijdicks EFM et al. *Neurology* 2010;74:1911-1918



# Brain Death: Medical Controversies

- One or two examinations?
- Value of ancillary (“confirmatory”) tests
- Need for standardization
- Therapeutic hypothermia protocols
- Failure to accept by family members
- Religious opposition
- Organ transplantation issues

Bernat JL. *Nature Rev Neurol* 2013;9:164-173



# Controversies in Circulatory Death

- Brought to medical and bioethical attention by the need to determine death in a timely fashion for organ donation after the circulatory determination of death (DCDD)
- Each DCDD program determines death using its own protocol with much variation among protocols
- “Controlled” and “uncontrolled” DCDD

# Controlled DCDD: Paradigm

- Dying ICU patient on ventilator, usually with severe brain damage but not brain dead
- Family requests cessation of life-sustaining therapy according to patient's preference
- Family (patient) requests organ donation
- DCDD protocol times the ICU cessation of life-sustaining therapy to the OR readiness to accomplish donation

# Uncontrolled DCDD: Paradigm

- Sudden cardiac arrest in or out of hospital
- CPR conducted but discontinued because unsuccessful; patient declared dead
- Patient moved to OR for organ donation following consent process with surrogate
- Practiced in Europe but not in USA or Canada though experimental protocols ongoing

Munjal KG et al. *Hastings Cent Rep* 2013;43(1):19-26

# cDCDD: Controversies

- Principal contemporary controversy in organ donor death determination:
- Is the organ donor dead once the heart stops beating or how long must one wait?
  - Heart might be able to be restarted by CPR
  - By definition, death is irreversible
  - If not irreversible, does it violate death statute?
  - Should the “dead-donor rule” be suspended?

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President's Commission. *Defining Death*, 1981

# Death: Statute vs. Medical Practice

- UDDA or variation is law in every state
- Irreversibility is intrinsic to concept of death but UDDA did not define *irreversible*
- President's Commission used *irreversible* and *permanent* interchangeably
- Distinction between *irreversible* and *permanent* is critical to understand



# *Irreversible vs. Permanent*

- Two words often used synonymously but have an important distinction in *OED2*:
- ***Irreversible***: “cannot be undone; irrevocable” Absolute and univocal
- ***Permanent***: “continuing without change; enduring” Equivocal and contingent

# *Irreversible vs. Permanent*

- ***Irreversible***: cannot reverse using current, available technology
- ***Permanent***: will not be restored spontaneously or through intervention
- Set of permanently ceased functions encompasses those ceased irreversibly
- Permanence rapidly yields irreversibility

# Proving Circulatory Irreversibility

- Attempt to reverse by CPR and show that it is impossible; may be insufficient proof
- Await classical late signs of death, eg, rigor mortis and dependent lividity
- Await long interval without circulation (> 1hour at normothermia) after which all would agree that cessation was irreversible
- Each is unnecessary and undesirable

# Death Determination in cDCDD

- Permanent cessation of function is accepted medical practice standard in applying the circulatory-respiratory criterion of death
  - Hospitalized dying patient example
  - Physicians not required to prove irreversibility
- Permanence always produces incipient, rapid, and inevitable irreversibility
- Its use is inconsequential in outcome

# Medical Practice Standard

- Noncongruence between the permanence medical practice standard and the irreversibility biological standard
- Permanence yields earlier death declaration than irreversibility standard, thus used by physicians for social and practical reasons
- Permanence standard has not caused public outcry but is not well known by the public

# Critique of Permanent Cessation

- Death cannot be a contingent event that depends on physician action or inaction
- Examples of how irreversibility is contingent:
  - Discontinuation of CPR when unsuccessful
  - Recovery after ECMO bridge after failed CPR
- Brave new technological world where irreversibility is based on physician volition

Bernat JL. *Hastings Cent Rep* 2013;43(6): 25-33

# Auto-Resuscitation: Data

- Comprehensive review of published cases
- In planned withdrawal of life-sustaining therapy in the ICU as in controlled DCDD:
  - AR to PEA can occur up to 65 seconds later
  - No cases of return of circulation
- After failed CPR as in uncontrolled DCDD:
  - Auto-resuscitation to restored circulation can occur up to 7 minutes after CPR is abandoned

# Permanent Cessation in cDCDD

- At 5 minutes of asytle, respiratory and circulatory functions are lost permanently:
  - CPR will not be performed
  - Auto-resuscitation will not occur
- Prove loss and permanence:
  - Loss: no blood flow using Doppler or A-line
  - Permanence: > 2 minutes; preferably 5



# Dead-Donor Rule

- Multi-organ donor must be dead
- Cannot kill the donor to procure organs
- DDR is the ethical and legal foundation of organ donation
- John Robertson argued it is necessary to:
  - Protect vulnerable persons
  - Preserve public trust in physicians, donation
- Is respected in cDCDD

# Dead-Donor Rule

- Abandoning the DDR jeopardizes confidence in physicians and the donation system
- Public opinion data do not necessarily predict impact of abandoning DDR
- Study prominent donation scares
  - 1980 BBC *Panorama* program on brain death
  - 1997 CBS *60 Minutes* Cleveland Clinic “exposé”

Bernat JL. *N Engl J Med* 2013;369:1289-1291

# Conclusions: I

- The noncongruence between the biological and the medical approach to death determination turns on the distinction between the irreversible and permanent cessation of circulatory functions
  - **Biological approach** requires the irreversible cessation of circulation and respiration
  - **Medical practice approach** requires only the permanent cessation of circulation and respiration
  - **Legal standard (statute)** provides: “... in accordance with accepted medical standards...”

# Conclusions: II

Are DCDD donors dead when declared in DCDD protocols and therefore satisfy the dead-donor rule?

- **No** by the strict biological standard that requires irreversible cessation of function
- **Yes** by the normative medical practice standard that requires permanent cessation of function
- **Yes** by the statute that provides “...in accordance with accepted medical standards...”

# Future Directions: DCDD

- The optimal standard for death determination in DCDD is a policy decision that should be made by stakeholders: physicians, patients awaiting an organ, organ donor families, OPOs, and the public
- Current implicit and a few explicit cDCDD guidelines (eg, AAP) support using the permanence standard
- Protocols of uDCDD may use prospective brain death criteria with permanent cessation of brain functions

# Future Directions: DBDD

- Better education of medical personnel and the public
- More rigorous biophilosophical justification for the equivalence of “brain death” and human death by clarifying which emergent functions define the organism as a whole
- Greater consensus on societally acceptable accommodations for those who do not accept it
- Possible use of “permanent” cessation of brain function in uncontrolled DCDD

**Table.** Conceptual timeline from circulatory cessation to death.

Time* <sup>†</sup>	T3						
	T1	T2	T3(a) or T3(b)		T4	T5	T6
Event	Circulation ceases by clinical observation	Brain functions cease by clinical observation	Circulation ceases permanently (will not reverse)	Circulation ceases permanently (will not reverse)	Brain functions cease permanently (will not reverse)	Circulation ceases irreversibly (cannot reverse)	Brain functions cease irreversibly (cannot reverse)
Prerequisite	None; autoresuscitation remains possible	No brain circulation	CPR <sup>†</sup> was not and will not be performed, autoresuscitation impossible	CPR was performed and failed, was discontinued, and will not be resumed; autoresuscitation impossible	Autoresuscitation impossible; no brain circulation	Autoresuscitation impossible; CPR would be unsuccessful if attempted	No brain circulation or no brain function if brain circulation has been restored
Evidence	No pulse or heartbeat	Unresponsiveness Apnea Brain stem reflexes absent	Mechanical asystole: Absent systolic wave forms by A-line; or no aortic valve opening on echocardiogram; electrical asystole is sufficient but not necessary	T3(a) evidence	"Brain death" tests fulfilled <sup>§</sup> ; absent intracranial blood flow, EEG and evoked potentials <sup>§</sup>	T3 evidence with electrical asystole	"Brain death" tests fulfilled <sup>§</sup> ; absent intracranial blood flow, EEG and evoked potentials <sup>§</sup>

EEG, Electroencephalogram.

\*T2 may follow T3 and T5 may follow T6 in some cases.

<sup>†</sup>T3(a) and T3(b) are alternatives for time T3. T3(a) is T3 when CPR is not performed, such as in cDCDD; T3(b) is T3 when CPR is performed but fails, such as in uD-CDD. Death determination using circulatory tests usually is made at T3 in organ donation and nondonation circumstances.

<sup>†</sup>CPR encompasses all attempts to restore circulation, including ECMO with warm oxygenated blood that perfuses the heart and brain.

<sup>§</sup>If tested.