

Ethical Issues in Circulatory Death Determination

New England Organ Bank
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Disclosures

- Paid Editorial Boards
 - *Physicians' Index for Ethics and Medicine*
- Royalties
 - *Ethical and Legal Issues in Neurology* (Elsevier, 2013)
 - *Ethical Issues in Neurology*, 3rd ed (LWW 2008)
 - *Palliative Care in Neurology* (Oxford, 2004)
- National/International Committees
 - *DHHS HRSA Panel on Determining Circulatory Death*
 - *WHO Clinical Criteria for the Determination of Death*

Objectives

- Ethical Issues of Consent:
 - Explain the elements of informed consent
 - Highlight the shortcomings of current practices
- 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

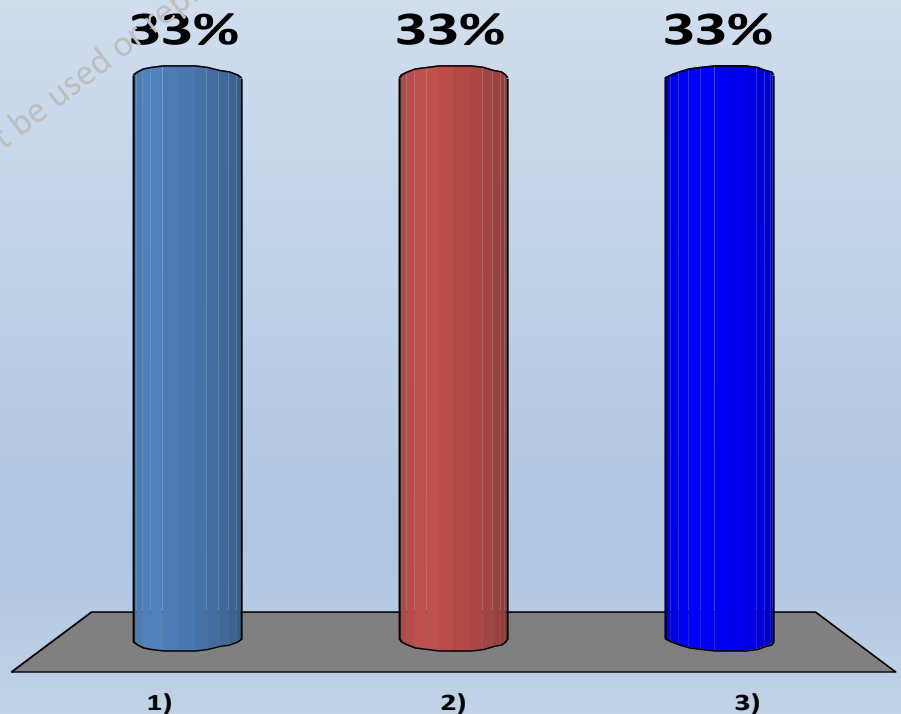
Controlled DCDD: Consent Issues

- First-person consent
 - Capacity, information, prognosis, end-of-life care
- Surrogate consent
 - How can surrogates render such a decision?
- Pre-mortem interventions
 - Heparin, ECMO catheters
- Post-mortem interventions
 - ECMO; restricted pelvic ECMO circuit

Overby KJ et al. *Am J Bioethics* 2015;15(8):3-9

Is first-person or surrogate consent for cDCDD ethically adequate, the way it is obtained in the protocol in your hospital?

- 1) Yes
- 2) No
- 3) Not sure



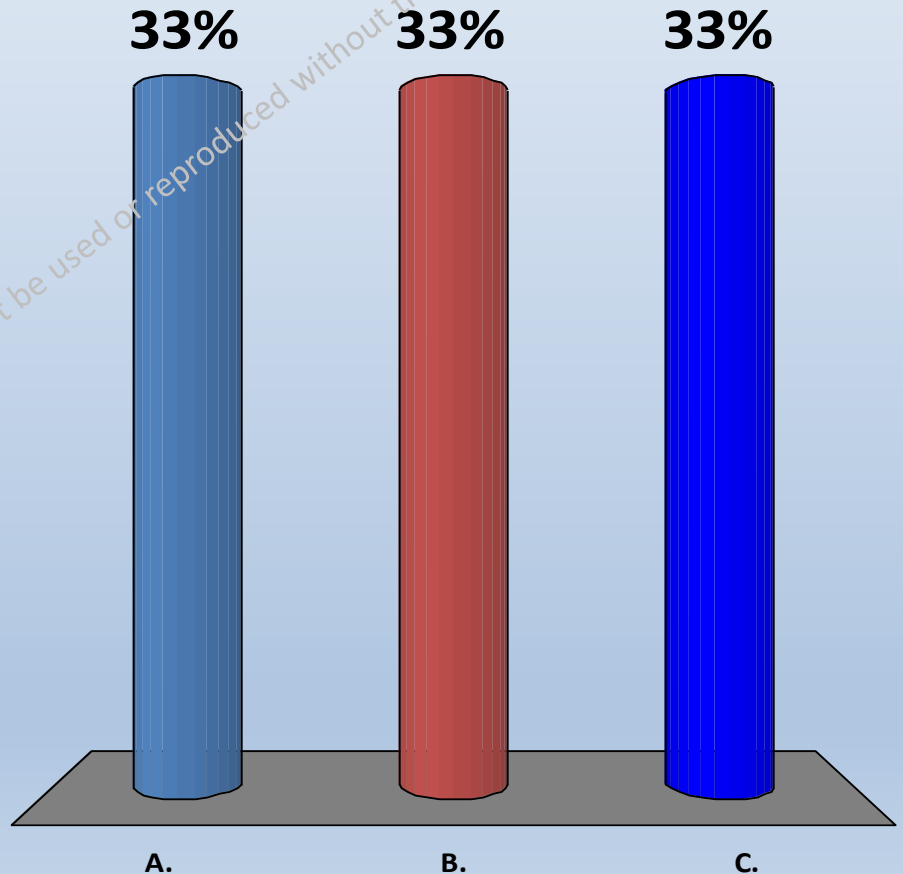
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CDCDD: Principal Ethical Issue

- Is the cDCDD donor dead at the moment death is declared in the protocol?
 - After 2 minutes of mechanical asystole
 - After 5 minutes of mechanical asystole
 - After 10 minutes of mechanical asystole
 - After 70 seconds of mechanical asystole
 - Only after long enough for brain death to ensue

Is the cDCDD donor truly dead at the moment that the donor is declared dead in your hospital's protocol

- A. Yes
- B. No
- C. Not sure



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
 - 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

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

Uncontrolled DCDD: Problems

- After failed CPR, is the patient really dead?
- Two cases raise question of irreversibility:
 - Acute MI with cardiac arrest and failed CPR
 - Patients placed on ECMO for several days until stunned myocardium regained heartbeat
 - Patients neurologically normal at discharge
- Should failed CPR patients be declared dead and offered as candidates for uDCDD, or placed on ECMO with hopes of good outcome?

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?

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

Hornby K et al. *Crit Care Med* 2010; 38:1246-1253

Permanent Cessation in cDCDD

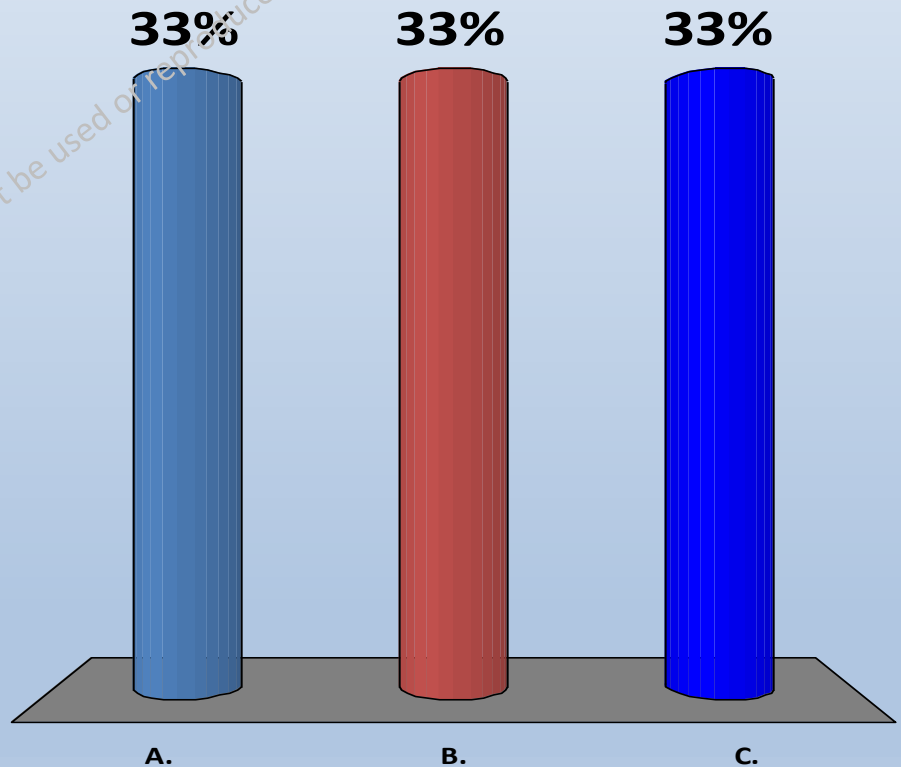
- At 5 minutes of asystole, respiratory and circulatory functions are lost permanently:
 - CPR will not be performed
 - Auto-resuscitation will not occur
- Prove loss and permanence:
 - Loss: no blood flow using Doppler or A-line
 - Permanence: > 2 minutes; preferably 5

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

Should the Dead Donor Rule be maintained in cDCDD, even if doing so reduces the number of organs transplanted?

- A. Yes
- B. No
- C. Not sure



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?

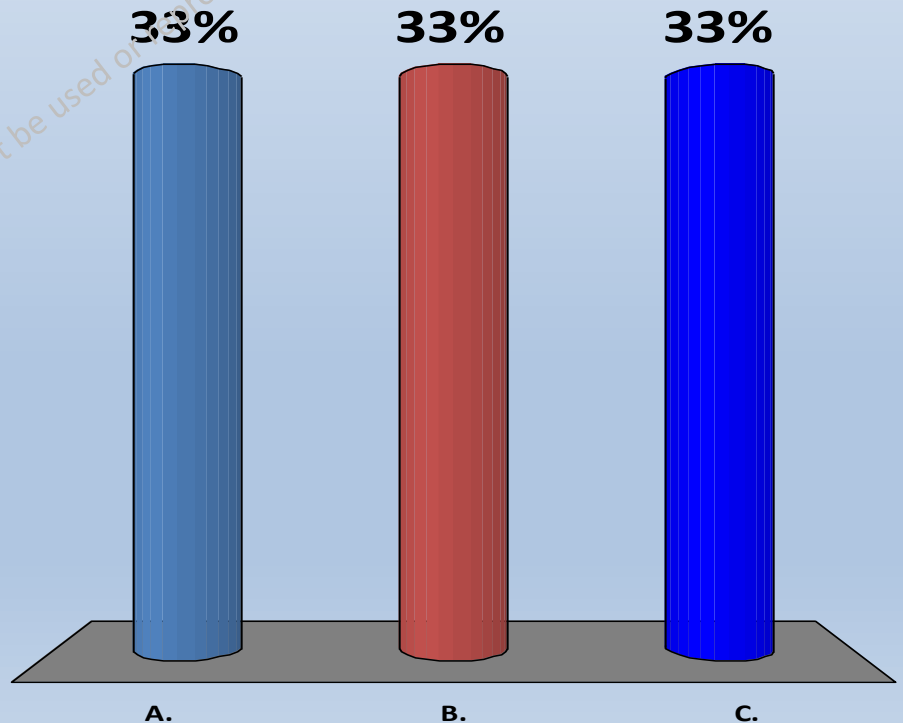
- **No** by the strict biological standard that requires irreversible cessation of function
- **Yes** by the normative medical practice standard that requires permanent cessation of function
- **Yes** by the statute that provides “...in accordance with accepted medical standards...”

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

Is the cDCDD donor truly dead at the moment that the donor is declared dead in your hospital's protocol?

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