

REANIMATION AFTER CIRCULATORY DEATH:

NEW OPPORTUNITIES, ETHICAL AND LEGAL CHALLENGES FOR ORGAN PROCUREMENT

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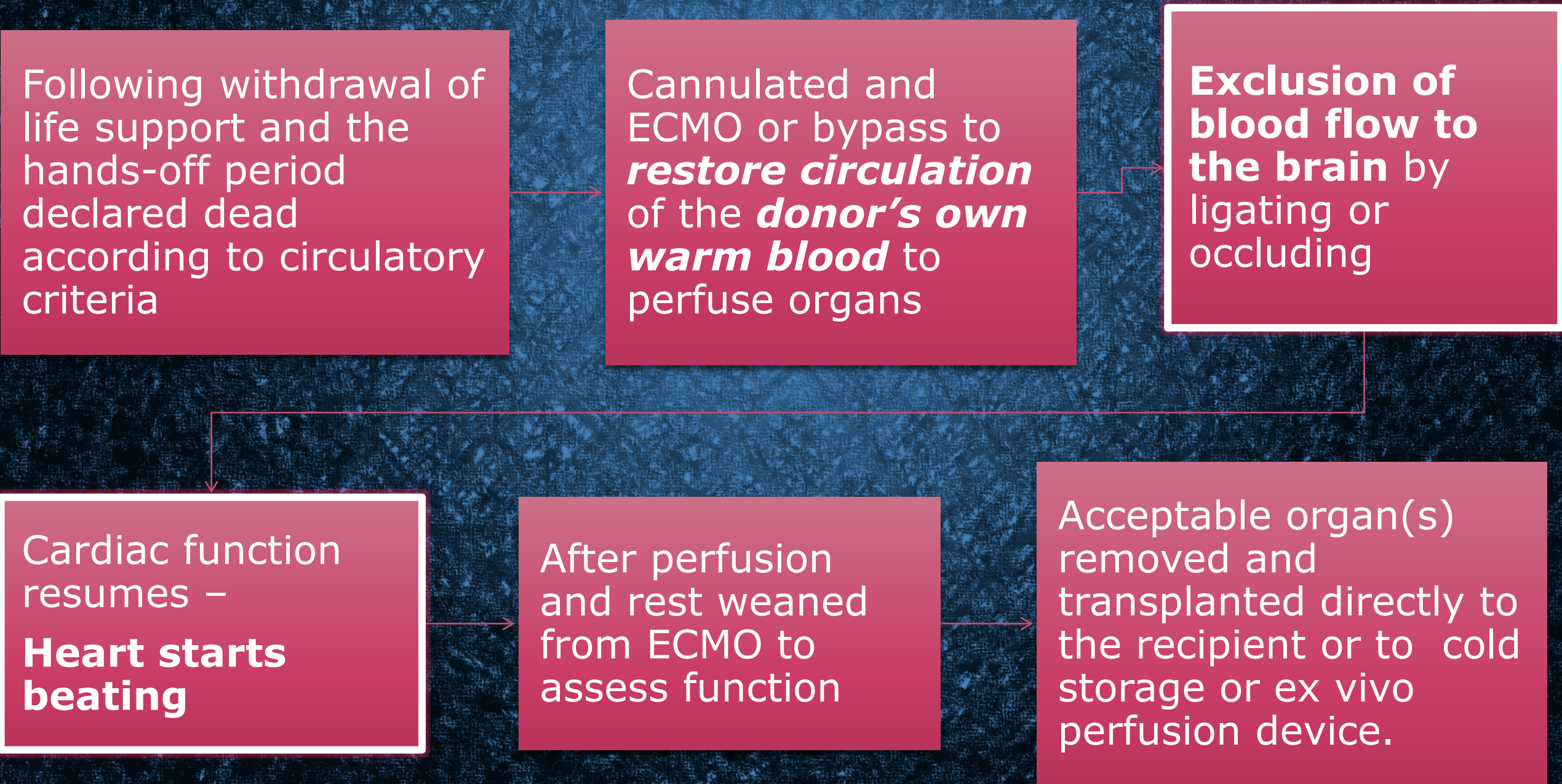
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CONTEXT & DEFINITION

- **Context:**
 - Donation after circulatory death (DCD) vs. death by neurological criteria/brain death (DNC)
- **Normothermic Regional Perfusion (NRP):**
 - Decedent's oxygenated blood pumped through thoracic and abdominal organs
 - Circulation and cardiac function restored
 - Allows time for further evaluation of organ function prior to acceptance for transplantation and procurement.
 - Abdominal vs. Thoracic

PROCESS TA-NRP



THE TWO PERSPECTIVES

PROPONENTS

- Quantity and quality of organs
- Maximizes organ donation
- Aligns donors' wishes and family's willingness

Critics

Violates the **Dead Donor Rule** (DDR)

Conflicts with the **Uniform Declaration of Death Act** (UDDA).


The threshold (irreversible cessation) not met

Restoring circulation retroactively negates declaration of death

ETHICAL CHALLENGES

Fundamental ethical and legal questions about compliance with DDR and the definition of death

Commentators invoke aspects Principlism, Utilitarianism, the principle of Double Effect and Kantianism

The background features a dark blue gradient with a pattern of stylized human figures in various shades of blue and white. The figures are simple, blocky shapes representing people in different poses, some with arms raised, creating a sense of a diverse group or community.

AUTONOMY- RESPECT FOR PERSON

PROPONENTS

- Respects patients' autonomy
 - Fulfills desire to donate/help someone else
 - Ensures organ quality
- Preventing blood flow to the brain
 - Respects donor's goals and wish to be a donor

Critics

Autonomy ***does not supersede*** other ethical and legal considerations

- ⊘ Contraindicated interventions on demand
- ⊘ Actions that violate law
- ⊘ Override DDR

Respecting autonomy **requires**:

Transparency and Informed Decision-Making

TRANSPARENCY and INFORMED CONSENT

Both sides acknowledge a need for transparency and informed consent but no agreed upon standard regarding how much detail to provide

(Parent et al.)

PROPONENTS

- No need for special/specific consent
 - Family driven
- Donors/families do not need to be informed about the risk of brain blood flow

Critics

Non-disclosure undermines :

Informed consent

Informed decision-making

Potential donors, recipients, donor's family unaware of what is involved

May violate values or religious beliefs

If subsequently learn about process may suffer distress

Increase public mistrust

Organ Procurement and Transplantation Network (OPTN) ETHICS COMMITTEE

Suggests

In the interest of *public trust, respect for persons,* and transparency, *authorizations should include disclosure of recirculation* through the heart (TA-NRP) and the *potential restoration of cerebral perfusion* as well as consideration of *meaningful difference* from other donation approaches.

- (Cole et al)

BENEFACTENCE

AND

NON-MALEFACTENCE

PROPONENTS

Beneficence

- Applies to recipient physiologically
- Organ quantity & quality
- Family meaning-making
- Patient legacy

Nonmaleficence

- No harms to patient: procedure on decedent
- Occlusion of blood flow
 - Ensures insentience
 - Regional circuit

Critics

Brain blood flow can occur - collateral blood flow, anatomical variations, technical failures

Potential for pain and suffering during procurement

(Cole et al; Glannon)

JUSTICE

Critics

Risk disproportionate impact stigmatized populations affected by the opioid epidemic

DCD more common in overdose death compared to other donors

(American College of Physicians)

PROPONENTS

- Undue burdens on certain populations is lacking evidence
- Withholding advanced procedures
 - Impacts recipient outcomes
 - Perpetuates known disparities in organ allocation.

DOUBLE EFFECT

Guideline for determining when permissible to pursue course of action that has one good effect but also a bad effect

Can allow an action with a foreseen bad outcome even though impermissible to pursue that if intent to produce the bad outcome

PROPONENTS

- The good: Organ viability
- Negative consequence: death is foreseen possibility
- TIMING: The good of organ viability is as immediate and the death

Critics

The ***intent*** of occluding cerebral vessels is **not** to prevent pain/suffering

Death is more than foreseeable side effect

Intent is to create brain death to avoid violating the DDR

Difficult to distinguish between harms foreseen as side effects and harms that are so close that they must be intended

Morally wrong according to the Principle of double effect

KANTIAN: SECOND CATEGORICAL IMPERATIVE

Always treat people as an end

Never as a means to an end

Never as a tool or an instrument to get something

Critics

NRP-cDCD violates Kant's Second Categorical Imperative to never use one individual merely as a means to serve the ends of another

No matter how good those ends

(American College of Physicians)

PROPONENTS

- Lazaridis: No person is treated as a means
- Only live (recoverable) organs of a decedent

UTILITARIAN

Utility considers goods and harms

The probability of various outcomes

The maximization of benefit to community.

(Cole et al)

PROPONENTS OF UTILITY

- Increased use of organs
- Improved recipient outcomes
- Society benefits – for the greater good

Critics

Potential for utility alone \neq ethical

Must balance utility against other considerations

Potential harm to donors

Ethical and legal uncertainties

↑ public mistrust → ↓ organ donation

Healthcare professionals' moral distress

(Cole et al.; Wilkinson and Savulescu)

The image features a background of a light blue ECG (heart rate) line on a grid. A dark blue rectangular box with a white border is centered on the page. Inside this box, the words "DEAD DONOR RULE" are written in a bold, white, sans-serif font.

DEAD DONOR RULE

Ethical principle

Embedded but not codified in law

Formulated by John A. Robertson in 1999

DDR Requires that:

- (1) patient must be declared dead before procurement of vital organs for transplantation
- (2) the act of organ procurement cannot occur before the death of the patient

PROPONENTS

- NRP temporarily restores circulation to a thoracic-abdominal region
- There are no attempts to resuscitate the decedent
- Only reducing ischemic time
 - Reperfusion
 - Reanimation
 - Evaluation
 - Procurement

Critics

Patient declared dead with full intent and understanding that ***circulation*** will be ***restored before procurement***

May meet criteria for ***determining death*** at time of death declaration, but ***invalidated*** when ***circulation is restored***

Does exclusion of blood flow to the brain cause of death?

(Entwistle et al.; Khan and Klitzman)

PREVENTING BLOOD FLOW TO THE BRAIN



Potential for resumption of blood flow to the brain an issue in postmortem restoration of circulation

Important since any brain stem function might negate a declaration of death

Ligating is ethically controversial

(Entwistle et al.; Domínguez-Gil et al)




PROPONENTS

- Cause of death is **underlying** disease/injury
 - TIMING: Cerebral ligation comes **after** death
- Donor **trajectory** is death
 - With or without cerebral ligation of arteries
 - With or without organ procurement
- Organs are no longer necessary for life
 - Procurement not cause of death

CRITICS

- The American College of Physicians (ACP) termed NRP-cDCD a ***“protocol more accurately described as organ retrieval after cardiopulmonary arrest and induction of brain death”***
- ***“Deliberate act”*** that ***causes*** the donor ***to become brain-dead*** so donor **still considered dead** after restoring circulation
- Interrupting circulation to the brain does not simply allow nature to take its course - ***medicine is intervening to ensure death***
- Is transplant team complicit in patient’s death?

• (American College of Physicians; Entwistle; DeCamp et al.;



**UNIFORM DECLARATION
OF DEATH ACT
(UDDA)**

The Uniform Declaration of Death Act states:

“An individual who has sustained either:

(a) irreversible cessation of circulatory and respiratory functions; or

(b) irreversible cessation of all functions of the entire brain including the brain stem is dead. ”

UDDA does not specify medical criteria for determining death because the accepted medical standards evolve

Determination of death is in accordance with acceptable medical standards



Model law authored by Uniform Law Commission

UDDA not a federal law

Each state must adopt and enact as a statute

Florida law reflects UDDA Florida Statute

§765.511(4) and

382.009 (1)



Florida Law

Florida Stat §765.511(4) death determined, in accordance with currently accepted medical standards, by the irreversible cessation of all respiration and circulatory function or as determined, by the irreversible cessation of the functions of the entire brain, including the brain stem.

Florida Stat. 382.009 (1) where respiratory and circulatory functions maintained by artificial means of support death may be determined the irreversible cessation of the functioning of the entire brain, including the brain stem

PROPONENTS

- *Circulatory death is permanent, even if reversible*
 - Regional circulation is not resuscitation
- Reversibility relates to function of organ in the organism **as a whole**
 - Cellular activity can no long contribute
- The organ cannot function within the person
- The person is dead even if the organ functions within another person

CRITICS

- ***Restarting circulation*** after death according to circulatory criteria ***challenges the legal definition***
- ***Reverses the declared irreversible cessation***
- ***Nullifies a declaration of death according to circulatory criteria***
- ***UDDA silent –whether subsequent acts can invalidate declaration of death***

(Parent et al.; DeCamp et al.; Entwistle)



**IS INTENT A FACTOR IN THE
DETERMINATION OF DEATH?**

INTENT - PROPONENTS

- Donor/family intention appropriate and informed
- Accepted medical standards
- Intent behind decision to not resuscitate is essential in the meaning of permanent cessation.

Critics

Intent absent from the legal definition of death and irreversible cessation

Definition based on physical condition not anyone's intent

Even if intent is to preserve organs and not to resuscitate

Cannot separate from the biological reality of what actually happens:

Circulation and ***heartbeat are restored*** thus ***patient resuscitated***

(Glazier and Capron; Peled et al.)

RECOMMENDATIONS




- **Only under a research protocol** approved by an **Institution Review Board**.
- Protocols should include brain monitoring and **plan to abort if brain flow or activity detected**
- ***Special informed consent***, particularly in ***brain reperfusion and ligation*** obtained after thoroughly explaining the donation process, including every step of the procedure
- ***Public conversation and education*** are necessary, including **diverse communities about public's attitudes, beliefs and preferences** and how much detail should be shared regarding the organ recovery procedure

RECOMMENDATIONS


Revising UDDA to address disconnect between law and advances in technology and medical interventions



Redefinition of death solely to benefit transplantation could undermine public trust



Redefinition of death requires societal and legislative buy-in and should not be “top-down” decision imposed by medical community (Khan and Klitzman)



In 2023 the Uniform Law Commission considered revising UDDA, however put revision on pause

CLOSING

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