Brain Death in the Neonatal ICU

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My Background

- Neonatologist and Ethicist
- Focus on decision making
- Long term effects on the family
- Consent/counseling process

Outline

- Review Brain Death in the Neonatal Population
- Review the TADA and its application in the NICU
- Review ethical considerations surrounding:
  - Experimental and
  - Extraordinary interventions
BRAIN DEATH IN NEONATOLOGY

How is Death Defined?

"An individual (is dead) 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 brainstem.
A determination of death must be made in accordance with accepted medical standards."


Brain Death Specified

- Brain death is a clinical diagnosis based on the absence of neurologic function with a known diagnosis that has resulted in irreversible coma
- Coma and apnea must coexist
- Documentation of complete neurological examination including specified components mandatory
### Prerequisites as specified at Texas Children’s Hospital

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waiting period prior to 1st exam for BD</td>
<td>24 hours after resuscitation</td>
</tr>
<tr>
<td>Clinical Exam</td>
<td>Required</td>
</tr>
<tr>
<td>Core Temp</td>
<td>&gt;35°C (note therapeutic hypothermia)</td>
</tr>
<tr>
<td># of exams</td>
<td>2, even if CBF done; 1st determines that patient meets criteria, 2nd confirms that criteria fulfilled</td>
</tr>
<tr>
<td># of examiners</td>
<td>2 different specialties</td>
</tr>
<tr>
<td>Interval between exams</td>
<td>Term to 30d: 24 hr 31d-adult: 12 hr</td>
</tr>
<tr>
<td>Reduction of period between exams</td>
<td>Permitted if EEG or CBF c/w BD</td>
</tr>
<tr>
<td>Apnea testing</td>
<td>2 unless clinically prohibitive</td>
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</tbody>
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### Continued

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
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<tbody>
<tr>
<td>Final PaCO₂</td>
<td>60mmHg and 20 above baseline</td>
</tr>
<tr>
<td>Drug Holidays</td>
<td>Guidelines delineated</td>
</tr>
<tr>
<td>Hypotension/Metabolic disturbances</td>
<td>Should be corrected, especially if may influence neurologic exam</td>
</tr>
<tr>
<td>Ancillary Study</td>
<td>Required ONLY when apnea and clinical exam cannot be completed: Term-30d: CBF 31d-18yo: EEG or CBF</td>
</tr>
<tr>
<td>Time of Death</td>
<td>Time of second exam</td>
</tr>
<tr>
<td>Documentation</td>
<td>Note Templates</td>
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### Challenges in the NICU

- Cannot be used for neonates < 37 wks
- Differences in neurologic exam and response
- Low frequency of occurrence:
  - TCH: only 2 patients over a 5 yr period
  - Differences in brain metabolism, blood flow and response to injury
- Open sutures make increased ICP less common
Challenges in the NICU

- Apnea testing:
  - 100% O₂ may inhibit respiratory effort
  - Bradycardia may precede hypercarbia
  - Ancillary studies less sensitive
  - CBF 63% vs ECS 40%

Interactions with Family

- Does not require parental consent*
- Discussions should be had prior to 1st examination regarding the implications
  - Must ensure family understands that life sustaining treatments (LST) must be stopped after determination made
  - Discussion of forgoing LST after declaring patient brain dead potentially confusing
  - Family allowed to be present

Key Points to remember

- Brain death is a medical diagnosis
- Does NOT apply to any neonate less than 37 weeks gestational age
- Examination does not require parental consent
- Important to keep organ procurement and brain death separate
TEXAS ADVANCE DIRECTIVES ACT & OTHER LAWS

Who was Baby Doe?

A: Bambi’s sister
B: John and Jane Doe’s little bundle of joy
C: The patient who’s case was most responsible for modernizing neonatal ethics

Baby Doe: Background

1982: Infant with Down Syndrome, TEF
Physicians could not agree on plan
Understanding of condition inadequate
Parents elected comfort care
Hospital sued to transfer
IN court supported parents
Baby died before appeal to Supreme Court
History Lesson
For those born after Bicentennial

- Who was POTUS in 1982?
  - Ronald Reagan

- Who was his Surgeon General?
  - Dr. C. Everett Koop

- What was Dr. Koop’s specialty?
  - Pediatric Surgery – extensive experience with TEF

Baby Doe Regulations

- DHHS created Baby Doe Regulations
- Health care providers could lose federal funds for withholding treatment from handicapped infants solely due to their handicap
- Rewritten multiple times in consultation with AAP, other interest groups
- Overturned by Bowen v AHA: lack of parental consent provided second reason

CAPTA Amendment

- Child Abuse Prevention and Treatment Act’s definition of child abuse changed
- Failing to provide “medically indicated” treatment for life-threatening conditions, except when:
  - Patient is chronically and irreversibly comatose; or
  - When providing treatment merely prolongs dying, would be futile in terms of survival, would not be effective in at correcting or ameliorating all of the infant’s life-threatening conditions; or
  - Would be ultimately futile and inhumane
Determination of Death
Texas Health & Safety Code §§ 671.001-.002

(a) A person is dead when... there is irreversible cessation of the person's spontaneous respiratory and circulatory functions.

(b) If [LST] preclude(s) a determination that a person's spontaneous respiratory and circulatory functions have ceased, the person is dead when... there is irreversible cessation of all spontaneous brain function.

Texas Advance Directives Act

- Establishes process for physicians to withdraw LST for a patient
- Even against the family's wishes
- Provides legal protection
- LST: sustains the life of a patient and without which the patient will die
  - Includes "artificial nutrition and hydration"
  - Excludes measures to provide comfort care
- Subject to applicable federal law relating to child abuse and neglect
Texas Advance Directives Act

- Attending must determine that patient meets the definition for one of two conditions to qualify under TADA
  - Terminal Condition
  - Irreversible Condition
  - No mention of futility
  - Defining futility is...
  - Patients are presumed alive
    - Brain dead patients are dead, therefore not covered

Terminal Condition

- Incurable condition caused by injury, disease, or illness that according to reasonable medical judgment will produce death within six months, even with available life-sustaining treatment provided in accordance with the prevailing standard of medical care

Irreversible Condition

- Condition, injury, or illness:
  - (A) that may be treated but is never cured or eliminated;
  - (B) that leaves a person unable to care for or make decisions for the person’s own self; and
  - (C) that, without life-sustaining treatment provided in accordance with the prevailing standard of medical care, is fatal
Irreversible Condition

- Condition, injury, or illness:
  - (A) that may be treated but is never cured or eliminated;
  - (B) that leaves a person unable to care for or make decisions for the person's own self; and
  - Prognostic ability important
  - Some advocate for less demanding standard
  - (C) that, without life-sustaining treatment provided in accordance with the prevailing standard of medical care, is fatal

Application in Adults

- Develop Terminal or Irreversible Condition
- Patient Issues Directive
- Attending determines if patient qualifies
- Initiates process of forgoing LST

Application in Minors

- Minor develops terminal or irreversible condition
- Attending determines if patient qualifies*
- Legal Guardian issues directive (verbal/non-verbal)
- Attending initiates process of forgoing LST

*Only occasionally possible before birth
Usually determined after evaluation in NICU
**TADA: Impending Death**

- What if patient is dying?
  - If there are no treatment options which may be reasonably expected to sustain life, then the TADA is not pertinent

**TADA: Out of Hospital DNR**

- "A competent person may at any time execute a written out-of-hospital DNR order directing health care professionals acting in an out-of-hospital setting to withhold cardiopulmonary resuscitation and certain other life-sustaining treatment designated by the board."

**TADA: Forgoing LST**

- What if the patient qualifies under TADA, but the parents refuse?
  - Detailed process by which the physician may forgo LST and remain protected by the law
TADA: Process
- Case referred to hospital ethics committee
  - LST continued for duration
  - Guardian must be informed of committee meeting at least 48 hours prior
  - Guardian may attend meeting
  - Must receive written explanation of committee’s decision

TADA: Process
- If committee agrees that continued LST is not indicated:
  - Guardian has 10 days to find a physician or hospital willing to accept
  - Hospital and physician must make reasonable efforts to assist in identification and transfer
  - After 10 days and if no accepting hospital or physician is identified, LST may be discontinued
  - Hospital and physician are protected from civil and criminal actions

Key Points
- The TADA is subject to CAPTA
- Patient must have an irreversible or terminal condition to qualify
- TADA delineates a process by which a physician/hospital may forgo LST against a family’s wishes
  - Provides legal immunity to physician/hospital
EXPERIMENTAL AND EXTRAORDINARY TREATMENT IN THE NICU

Ordinary Care
- Ordinary care is that which offers greater benefits vs burdens
  - What physicians are obligated to provide
  - Standard of care considered ordinary
- Context specific
  - ECMO for persistent pulmonary hypertension vs Surfactant Protein-B deficiency
  - Amputation for gangrene vs cellulitis

Extraordinary Care
- Extraordinary care goes beyond this
- Burdens outweigh the benefits, or there are no expected benefits
  - Burdens may not be patient centered
    - Costs to family, society, etc.
- Context specific
  - ECMO for PPHN vs SP-B deficiency
  - Amputation for gangrene
Obligations

- Since extraordinary care goes beyond what we are expected to provide
  - Under no obligation to offer it
- Parents are also under no obligation to accept it
- Treatment which has no proven benefit, and is not the standard of care, but may be reasonably assumed to provide greater benefits than burden, is experimental

Experimental Treatment

- Unproven treatment which may or may not benefit the patient
- Burdens to patient may be known or unknown
- If being offered, the family must be informed of the experimental nature, and permitted to decline
- If consistent practice, should seek IRB approval

Experimental Treatment

- Physicians are under no obligation to offer or provide experimental (or extraordinary) treatment
- If family requests if experimental treatment available, permissible to advise them
  - Stress unknown outcomes, and possible outcome being worse after experimental treatment
Key Points

- Extraordinary care either burdens the patient more than benefits, or it provides no reasonable expectation of benefit
- No obligation to provide, and families have no obligation to accept extraordinary or experimental care

QUESTIONS?