National Academics of Science, Engineering, Medicine

Committee on Organ Donor Intervention Research

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Disclosures

• Director of Division Neurocritical Care, Department of Neurology at the Brigham and Women’s Hospital
  – Home of the world’s first successful organ donor then the first successful organ transplant in 1954.

• Medical Director for Critical Care at New England Organ Bank
Discuss

- Ethical principles relevant to the conduct of interventional research on deceased donors and deceased donor grafts

- Responsibilities to donors and donor families

- Responsibilities of donor hospitals
Reasons to declare Brain Death

• To ensure that inappropriate measures are not undertaken

• To provide finality for families unclear about prognosis

• To preserve vital critical care resources

• For possible organ donation
How do we make the diagnosis of death?
The diagnosis of death

Cardiac death (heart stops)
- Absence of radial, carotid or femoral pulses
- Absence of heart tones at apex of heart by auscultation
- Absence of breath sounds by auscultation
- Pupils nonreactive
- Ascertain that the patient does not rouse to verbal or tactile stimuli

Brain death (brain stops)
- Irreversible loss of function of the brain, including the brainstem
- Exam is much more complicated
- ICD 10 code G93.82
Practice Parameters published in 1995, based on the Uniform Determination of Death Act (UDDA) of 1981: “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 is made with acceptable medical standards.”

Uniform Determination of Death Act, 12 uniform laws annotated 589 (West 1993 and West suppl 1997)
Neurological History and Examination

- Establishment of the cause of coma
- Clinical/imaging evidence of acute CNS catastrophe compatible with the diagnosis
- Determination of irreversibility
- Resolution of misleading clinical neurologic signs
- Recognition of possible confounding factors
  - No drug intoxication or poisoning
  - Core temp. $\geq 36.5$ C (97F)
The Core of the Examination

Part I: Coma

Part II: Absence of brainstem reflexes

Part III: Apnea
Brain death is a clinical diagnosis.

Ancillary tests can be used when uncertainty exists about the reliability of parts of the examination or when the apnea test cannot be performed.
Brain Death Diagnosis

• Its easy not to go through the process of diagnosis

• Not mandatory

• There is no incentive other than the benefit to society
Variability of Brain Death Policies in the United States

David M. Greer, MD, MA; Hilary H. Wang, BA; Jennifer D. Robinson, APRN; Panayottis N. Varelas, MD, PhD; Galen V. Henderson, MD; Eelco F. M. Wijdicks, MD, PhD

**Importance** Brain death is the irreversible cessation of function of the entire brain, and it is a medically and legally accepted mechanism of death in the United States and worldwide. Significant variability may exist in individual institutional policies regarding the determination of brain death. It is imperative that brain death be diagnosed accurately in every patient. The American Academy of Neurology (AAN) issued new guidelines in 2010 on the determination of brain death.

**Objective** To evaluate if institutions have adopted the new AAN guidelines on the determination of brain death, leading to policy changes.

**Design, Setting, and Participants** Fifty-two organ procurement organizations provided US hospital policies pertaining to the criteria for determining brain death. Organizations were instructed to procure protocols specific to brain death (ie, not cardiac death or organ donation procedures). Data analysis was conducted from June 26, 2012, to July 1, 2015.

**Main Outcomes and Measures** Policies were evaluated for summary statistics across the following 5 categories of data: who is qualified to perform the determination of brain death, what are the necessary prerequisites for testing, details of the clinical examination, details of apnea testing, and details of ancillary testing. We compared these data with the standards in the 2010 AAN update on practice parameters for brain death.

**Results** A total of 508 unique hospital policies were obtained, representing the majority of hospitals in the United States that would be eligible and equipped to evaluate brain death in a patient. Of these, 492 provided adequate data for analysis. Although improvement with AAN practice parameters was readily apparent, there remained significant variability across all 5 categories of data, such as excluding the absence of hypotension (276 of 491 policies [56.2%]) and hypothermia (181 of 228 policies [79.4%]), specifying all aspects of the clinical examination and apnea testing, and specifying appropriate ancillary tests and how they were to be performed. Of the 492 policies, 163 (33.1%) required specific expertise in neurology or neurosurgery for the health care professional who determines brain death, and 212 (43.1%) stipulated that an attending physician determine brain death; 150 policies did not mention who could perform such determination.

**Conclusions and Relevance** Hospital policies in the United States for the determination of brain death are still widely variable and not fully congruent with contemporary practice parameters. Hospitals should be encouraged to implement the 2010 AAN guidelines to ensure 100% accurate and appropriate determination of brain death.
Prerequisites for Clinical Testing

- "Train of Four" 11%
- Absence of Hypotension 56%
- Absence of Confounding Med Cond. 74%
- Established Cause 83%
- Absence of Drugs 94%

Venn Diagram:
- Acid-Base (8)
- Endocrine (3)
- Electrolyte Disturbance (11)
- Drug Levels Mentioned?
  - Yes 25%
  - No 75%
Stipulated Clinical Exam Specifics

- Absence of Pupillary Reflexes: 93%
- Absence of Corneal Reflexes: 90%
- Presence of Coma: 90%
- Absence of Oculovestibular Reflex ("Cold Calorics"): 89%
- Absence of Oculocephalic Reflex ("Doll's Eyes"): 88%
- Absence of Gag Reflex: 87%
- Absence of Reaction to Deep Pain: 84%
- Absence of Cough Reflex: 79%
- Absence of Spontaneous Resp. (Prior to Apnea Testing): 62%
- Absence of Jaw Jerk Reflex: 23%
Apnea Testing Criteria

- # Liters of O2 Specified: 63%
- Absence of Respiratory Effort: 88%
- Pre-Oxygenation Specified: 79%
- Final pCO2 Specified: 69%
- ABG Prior: 66%
- pCO2 Level Above Baseline Specified: 59%
- Temperature Prior To Testing Specified: 45%
- Stop if Unstable: 64%

Pie Chart:
- "FiO2": 14%
- >6L: 25%
- 4-6L: 56%
- <4L: 5%

Venn Diagram:
- Hypotension: 14%
- Desaturation: 65%
- Arrhythmia: 12%

Why?
When to Perform Ancillary Testing

- Inability to complete exam: 51%
- Inconclusive sleep test: 49%
- Toxic drug levels: 52%
- Chronic CO2 retention: 14%
- Normal CT or MRI: 9%

Optional: 68%
Recommended: 17%
Mandatory: 5%
Other/Unclear: 10%

Which Ancillary Tests to Perform

- Electroencephalography (EEG): 79%
- Radionuclide Study (SPECT): 72%
- Conventional Cerebral Angiography: 71%
- Transcranial Doppler (TCD): 33%
- Evoked Potentials (SSEP): 25%
- Computed Tomographic Angiography (CTA): 9%

Recommended
Unproven
Brain Death Around the World

Wijdicks EFM. Brain death worldwide: Accepted fact but no global consensus in diagnostic criteria NEUROLOGY 2002;58:20-25

- Guidelines of 80 countries reviewed
- Legal standards on organ transplantation present in 69% (55 of 80 countries)
- Practice guidelines for brain death for adults in 88%
  - 50% guidelines require >1 physician to declare
  - All guidelines specified exclusion of confounders, presence of irreversible coma, absent motor response, and absent brainstem reflexes
  - Apnea testing required in 59%
  - differences in time of observation and required expertise of examining physicians
  - Confirmatory lab testing mandatory in 28 of 70 (40%) guidelines
Figure 1 Required absences of neurologic function for the declaration of brain death, by percentage of respondents.
Figure 2 Use of ancillary testing in the declaration of brain death worldwide.

Sarah Wahlster et al. Neurology 2015;84:1870-1879
Patients in NEED Growing Faster than Available Organs

OPTN, 7/2014
Hospital/Physician/Nurse Responsibilities

• Comply with the criteria for making a timely referral

• Ensure all potential donor families are informed by OPO representative of their donation opportunity

• Cooperate fully to support the donation process, including:
  – Maintaining organ viability
  – Conducting necessary tests

HIPAA Exception

Granted to all OPOs to facilitate the donation process
Donor Registry

“Yes” at the RMV is first-person consent and a legal document

• No need to mention registry status to family

• Timing of disclosure discussion is decided in collaboration with OPO
Who Is a Potential Donor?

- Dependent on many factors
- Fatal illness/injury
- Consideration for withdrawal of life support
Message In The Media
INTRODUCTION:
• We sought to evaluate the caliber of education mainstream media provides the public about brain death.

METHODS:
• We reviewed articles published prior to July 31, 2015, on the most shared/heavily trafficked mainstream media websites of 2014 using the names of patients from two highly publicized brain death cases, "Jahi McMath" and "Marlise Muñoz."

RESULTS:
• We reviewed 208 unique articles. The subject was referred to as being "alive" or on "life support" in 72% (149) of the articles, 97% (144) of which also described the subject as being brain dead. A definition of brain death was provided in 4% (9) of the articles. Only 7% (14) of the articles noted that organ support should be discontinued after brain death declaration unless a family has agreed to organ donation. Reference was made to well-known cases of patients in persistent vegetative states in 16% (34) of articles and 47% (16) of these implied both patients were in the same clinical state.

CONCLUSIONS:
• Mainstream media provides poor education to the public on brain death. Because public understanding of brain death impacts organ and tissue donation, it is important for physicians, organ procurement organizations, and transplant coordinators to improve public education on this topic.

'It was the hand of God at work': Meet brave teenage girl who suffered 'irreversible' brain injury and was pulled off life support but awoke from coma and made full recovery

- Taylor Hale, then 14, suffered traumatic brain injury when she fell off hood of car while horsing around with friends in 2011
- She spent a week in medically induced come to help her brain heal, but she suffered a brain hemorrhage
- Doctors declared Taylor brain dead and took her off life support, but hours later she woke up
- Right before Taylor came out of coma, a devout family friend visited her and prayed for her recovery
- Jeff Stickel, a chiropractor, laid his hand on Taylor's neck while praying with family
- Hale, now 17, will be graduating high school Monday

By SNEJANA FARBEROV FOR DAILYMAIL.COM
It was the hand of God': 'Brain-dead' girl who was pulled off life support AWAKES from coma after chiropractor's prayer session and makes full recovery
Walnut Creek hospital mistakenly diagnoses woman brain-dead

By Matthias Gafni and David DeBolt

Bay Area News Group

POSTED: 05/17/2016 03:01:28 PM PDT  |  UPDATED: 14 DAYS AGO
Parents: Brain-dead toddler moved to facility outside U.S.

Staff, ABC10, KXTV  2:01 PM PDT May 23, 2016

Editor’s note: Israel Stinson was taken to multiple health care facilities for care, this story has been updated to clarify his treatment.

Parents of a toddler who was deemed brain dead are celebrating his transfer to a facility outside the United States.

Israel Stinson’s parents, Nate Stinson and Jonee Fonseca, brought their 2-year-old to a hospital in early April after a severe asthma attack. The boy, Israel Stinson, suffered cardiac arrest. He was transferred to Kaiser Permanente Roseville. When Nate and Jonee requested a feeding and breathing tube for Israel until he could be transferred to another facility, Kaiser officials denied the request because they believe Israel has irreversible brain death.

The fight over Israel’s care was going through the courts, and a decision expected last week had been delayed until Monday. Jonee posted on the family’s GoFundMe page Sunday evening with the update that Israel had been moved.

Chapman et al: a systematic review of 34 qualitative studies of family experiences regarding organ donation.

They reported that donor family members:

– Believed in the goodness of organ donation and that saving a life was worthwhile;

– Obtained comfort and relief as it allowed their loved one to live on;

– Provided a positive outcome that reduced grief and even was a cause for celebration.

Greser et al. interviewed donor family members and had them complete questionnaires regarding their donation decisions.

91% stated they would make the decision to donate again years later; only 1% of donor family members stated they would decline organ donation if they had it to do again.
My personal experience regarding Physician behavior in ICUs

• Patients who are going to die get the lowest priority in the ICU
• Many neurologists and intensivists feel uncomfortable with how to make the diagnosis
• There is difficulty with communication with the family
  – Trust is developed by style of communication
  – Brain death is used as a descriptive term of how bad things are rather than a diagnosis
Overall Suggestions

• Yes, research should occur in deceased donors and their organs
• Standardize the process for declaration
• Make in mandatory
  – Consider a certification process and the use of simulation for training
• Improve communication between coordinators and physicians and families
Role of the Physician

“Pour guérir parfois,  
Pour soulager souvent,  
Pour consoler toujours.”

“To cure sometimes,  
To relieve often,  
To comfort always.”

15th C French saying