Follow up to Recommendation 56 from the ACOT Brain Death Workgroup

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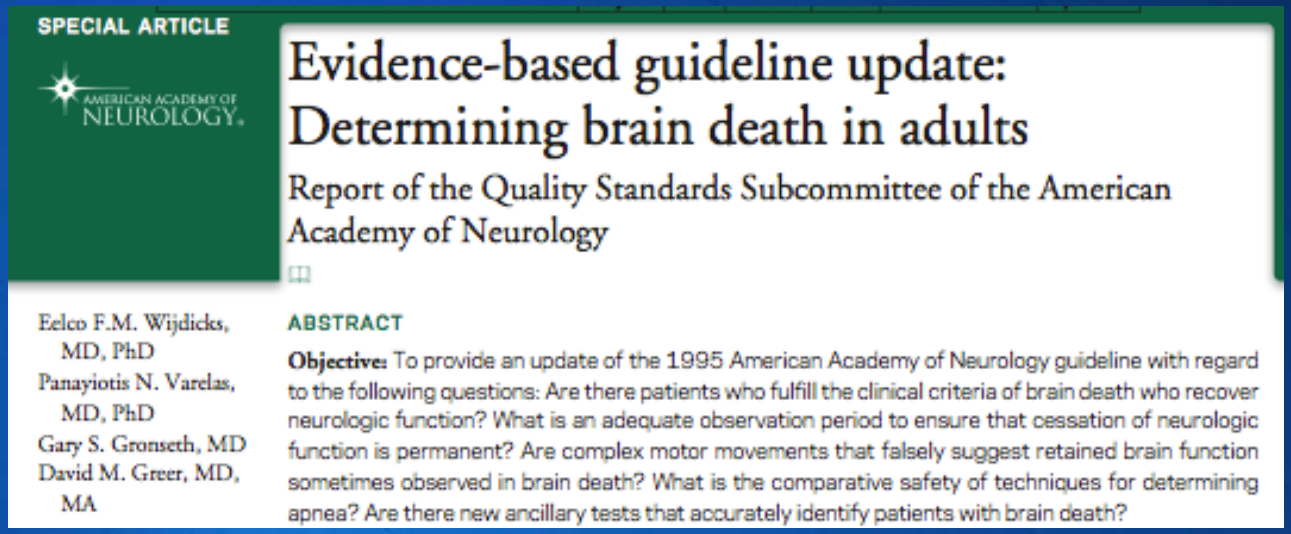
Background

- Recommendation 56 was intended to provide standardization to determine neurologic death using existing national adult and pediatric guidelines
- ACOT recognized the importance of this recommendation given inconsistent practices and the lack of a national regulatory standards for determination of brain death
- ACOT encouraged adoption of national guidelines for determination and documentation of brain death in infants, children, and adults

Background (cont.)

- National guidelines for adults and children



SPECIAL ARTICLE

AMERICAN ACADEMY OF NEUROLOGY

Evidence-based guideline update: Determining brain death in adults

Report of the Quality Standards Subcommittee of the American Academy of Neurology

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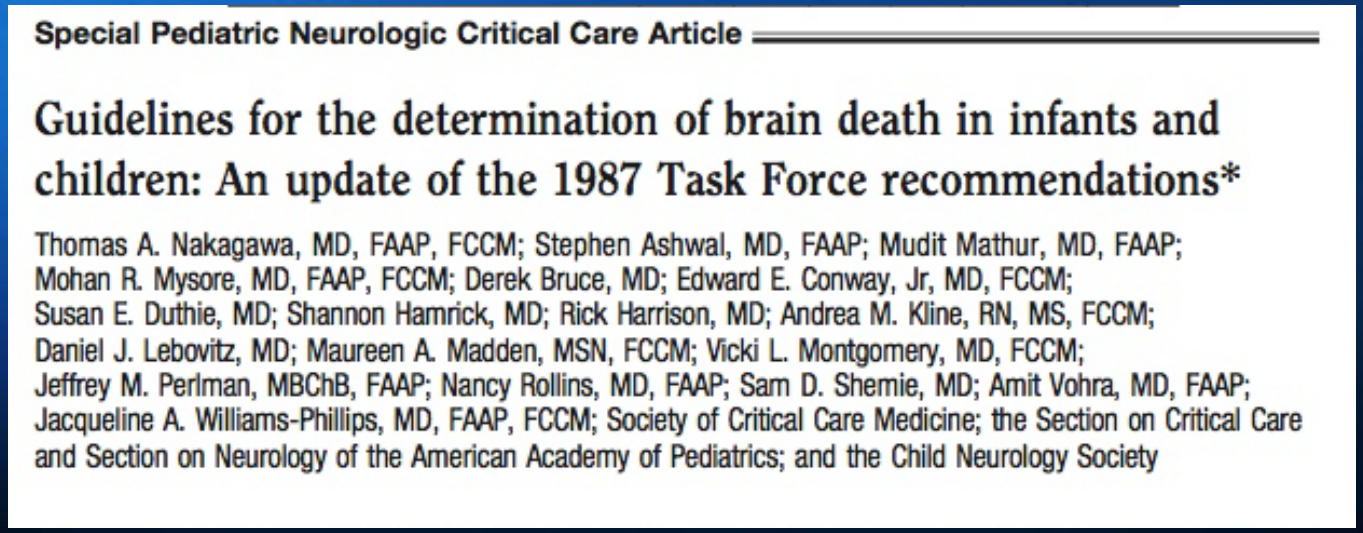
ABSTRACT

Objective: To provide an update of the 1995 American Academy of Neurology guideline with regard to the following questions: Are there patients who fulfill the clinical criteria of brain death who recover neurologic function? What is an adequate observation period to ensure that cessation of neurologic function is permanent? Are complex motor movements that falsely suggest retained brain function sometimes observed in brain death? What is the comparative safety of techniques for determining apnea? Are there new ancillary tests that accurately identify patients with brain death?



Special Pediatric Neurologic Critical Care Article

Guidelines for the determination of brain death in infants and children: An update of the 1987 Task Force recommendations*

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Recommendation 56

- The following recommendations were made by ACOT to the Secretary in Recommendation 56
  - The Medical community use currently accepted guidelines that have been endorsed and supported by multiple national medical organizations for the determination of brain death in infants, children, and adults. These brain death guidelines should be used by clinicians tasked with determining brain death.

Recommendation 56 (cont.)

- The potential donor patient must have a documented clinical examination (including a valid apnea test) as determined by currently accepted adult and pediatric brain death guidelines to make the determination of death. In situations where a complete clinical examination and apnea test cannot be performed, the patient must have an approved ancillary test that is consistent with brain death.
- Documentation must support the determination of death as outlined in currently accepted adult and pediatric brain death guidelines.

Recommendation 56 (cont.)

- All hospitals should have brain death policies in place that reflect currently accepted adult and pediatric brain death guidelines. Hospital policies should be reviewed and revised accordingly.

  It is recommended that OPOs review hospital brain death policies on a periodic basis and provide the hospital with resource information on currently accepted guidelines for the determination of death in adults and children.

Recommendation 56 (cont.)

These policies will assist by allowing definitive documentation of the specific steps and timeline to determine and declare brain death for clinical and medical legal purposes. The OPO should verify that documentation of brain death examination is consistent with applicable hospital policy to determine death for all potential donors.

Recommendation 56 (cont.)

- To maximize the potential for donation opportunities and provide quality end-of-life care, determination of death should be performed in a timely manner in any patient where brain death is suspected. This includes timely referral to the OPO in an effort to preserve donation options for the family or legal guardian. In situations where an observation period occurs between examinations, patients should be medically supported until declared dead by neurological criteria, or until medical support is withdrawn.

Recent events

- A high profile California case last year involved a pediatric patient determined legally dead by neurologic criteria using currently existing medical guidelines
- Based on the family's court petition to prevent withdrawal of artificial mechanical support, medical support was sustained for this child despite being declared legally dead
- The family was able to transfer the child's body to another facility out of state that purportedly agreed to maintain artificial support

Jahi McMath, Girl Left Brain Dead From Routine Tonsillectomy, To Be Kept On Life Support

By TERRY COLLINS 12/21/13 02:35 AM ET EST AP

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The legal definition of death

- Death is defined by state law
- Uniform Determination of Death Act
  - Irreversible cessation of
    - Circulatory function
    - Whole brain
  - In accordance with accepted medical criteria
- Defining death versus defining how death must be diagnosed
- Balancing the need for certainty and the flexibility the practice of medicine requires

The legal issues

- Disagreement over the diagnosis or over the definition of death
- Court intervention likely to result in a temporary restraining order (TRO)
  - Allow for second opinion
  - Balancing of the harms
- Hospitals have no legal obligation to keep a deceased patient on ventilator support unless donation is planned
- 2 states have religious exemption

Ramifications of this case

- Potential immediate and long term consequences of continued support of a body after being declared legally dead
  - Inappropriate utilization of medical resources caring for a deceased patient when donation is not planned
  - Emotional conflict for families and hospital staff
  - Denial for organ donation and loss of potential donors resulting in fewer recovered organs for transplantation

Ramifications of this case (cont.)

- Can processes be implemented to reduce the likelihood of avoiding potential future cases similar to this?
  - Recommendation 56 states: *"These (hospital) policies will assist by allowing definitive documentation of the specific steps and timeline to determine and declare brain death for clinical and medical legal purposes."*
  - Recommendation 56 does not mention when medical therapies should cease when donation is not planned following death

Questions for discussion

- Should Recommendation 56 be amended to provide more clarity ?
  - *"when death has been legally declared, medical therapies cease unless donation is planned"*

- Could ACOT make a recommendation that CMS require hospitals to have stronger policies in place regarding protocol following determination of death by neurologic criteria?

Considerations

- Is it appropriate for ACOT to make recommendations about regulatory guidance after death by neurologic criteria has been declared?
- Would this be perceived as a conflict of interest coming from ACOT?
- Are there other groups that should be considering this issue?
- Are there other potential unintended consequences if ACOT were to amend Recommendation 56?