Brain Death Determinations in New York State: Past and Present

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NYS Historical Perspective

- **PHL Article 43 (1970)**: NYS’s first organ donor statute
  - Deferred to physician discretion to determine “what and when is death”
  - Required two physicians to certify time of death for organ donors

- **People v. Eulo (N.Y. Ct. App. 1984)**: Recognizes that total and irreversible cessation of brain function satisfies the standard for determining death

- **Determination of Death (1986)**: *NYS Task Force on Life and the Law*
  - Recommends that the State recognize brain death as well as death by cessation of heart and lung functions
  - Proposed regulations (rather than new legislation, in light of *Eulo*)
  - Suggests hospitals develop policies for reasonable accommodation
NYS Historical Perspective (con’t)

10 NYCRR § 400.16 (1987)

- Recognizes brain death
- Directs hospitals to establish written policies for:
  1. required testing;
  2. notification of next of kin;
  3. reasonable accommodation

NYS Guidelines for Determining Brain Death:

- First released to support regulatory change; revised in 1997
- 1997 version based on consensus-conference in 1995
- Later calls for further revision due to newer clinical data and perceived lack of uniformity
Brain Death Guidelines panel convened by Task Force/ NYSDOH

- Consensus building process; relied on American Academy of Neurology (AAN) recommendations

- **Goals:**
  1. Provide information on requirements for determining brain death
  2. Increase knowledge among health care practitioners
  3. Decrease variation across health care facilities
  4. Increase public confidence that determinations are made after thorough examination, in accordance with accepted medical standards

- **Included:**
  - Clear process steps for declaring brain death
  - Information on the role of the 2nd physician in declaring and certifying brain death for organ donors
  - More extensive descriptions of confirmatory testing
  - A new clinical checklist
2011 NYSDOH Guidelines for Determining Brain Death

- **2010**: New calls for revising NYS’s guidelines
- **AAN**: Releases new article and recommendations in 2010
  - Comprehensive review of data and studies
  - New clinical recommendations
- **Outside panel of expert physicians**
- **Task Force on Life and the Law**:  
  - Consensus building processes
  - Clinical, ethical and legal review
  - Stakeholder input
2011 NYSDOH Guidelines (con’t)

- **NYSDOH** – Review and promulgation of draft guidelines
- **NYS Guidelines for Determining Brain Death:** Officially issued December 6, 2011
- **Letter from Commissioner Shah to Hospital CEOs**
2011 NYSDOH Guidelines (con’t)

- Reliance on a single, rigorous brain stem examination – rather than two examinations – prior to performance of an apnea test;
- New guidance on waiting periods;
- Updated information on ancillary testing;
- Clarification of the role of the second physician in certifying brain death for patients who are organ donor candidates; and
- Modifications of the clinical checklist
Waiting Period – 2005 Guidelines

- 6 hour waiting period between the first and second brain stem reflex examinations
- However, insufficient evidence to pinpoint a minimally-acceptable number of hours to ensure that brain function has permanently ceased.
- 6 hours as “arbitrary”
Waiting Period – 2011 Guidelines

- Physicians should wait an appropriate amount of time, sufficiently long as is relevant to the individual patient’s condition (in practice, usually several hours), after the onset of the brain insult to exclude the possibility of recovery.

- Requires that the possibility of recovery be ruled out prior to proceeding to the brain stem reflex exam.
Certifying Time of Death - Organ Donors

- **PHL § 4306**: Time of brain death - certified by physician who attends donor at death and one other physician, neither of whom shall participate in the procedures for removing or transplanting organ(s).

- **2011 Guidelines**: 2nd physician should “review and affirm that the medical record and data fully support the determination of brain death. Any aspect …may be performed again if the second physician believes it is indicated to make his or her determination concerning brain death.”