GIFT of LIFE
DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

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Pennsylvania House of Representatives
Judiciary Committee Hearing - House Bill 30
May 13, 2014

Good morning Chairman Cutler, Chairman White, and members of the Committee.

My name is Richard Hasz and I am the Vice President of Clinical Services at Gift of Life Donor Program Program. Thank you for providing me with the opportunity to speak with you today about the organ donation process and how House Bill 30 will help to increase donation and save lives.

Gift of Life Donor Program has been coordinating organ donation and transplantation in the eastern half of Pennsylvania for 40 years. That experience has allowed Gift of Life to develop clinical processes that represent best practices not only across the United States, but internationally as well. Unfortunately, clinical practice is not uniform across Pennsylvania counties and does not adhere to the most current national standards and federal regulations. House Bill 30 would ensure that clinical best practices are the norm in every hospital in every county in the Commonwealth. By doing so, we will ensure that donation opportunities are not wasted needlessly, and by coordinating more donations we will save lives. With more than 8,500 people waiting for a transplant in Pennsylvania, and with more than 400 of those people dying each year, it is essential that we pass House Bill 30 and do everything possible to address this public health crisis.

I. The Organ Donation Process

The following is an outline of the organ donation process in the Gift of Life service area. While the process in other service areas may vary slightly, much of what is described below is dictated by state and federal law.

1. Hospital Referral

Initial referral

Hospital medical staff determines that a patient is at or near death according to established hospital clinical policies. Hospital staff initiates required referral phone call to federally-designated organ procurement organization ("OPO").[1] Every PA hospital patient death is required to be referred to an OPO according to federal regulations. This information is also subject to extensive confidentiality requirements applicable to both the hospitals and the OPOs. Donor and recipient information is required to be maintained as confidential among the medical professionals involved in the process. Approximately 30,000 PA hospital deaths are referred each year to Gift of Life Donor Program with only an estimated 650 being potentially medically suitable to become an organ donor. There are currently over 8,500 people awaiting transplant in PA and on average more than 8 of them will die each week.

Phone screening

Hospital staff provides information to the OPO so a preliminary determination can be made by as to whether there is a potential for organ or tissue donation.

On-site evaluation

Where there is a potential for organ donation (patient has a non-survivable brain injury and is supported by a ventilator in the ICU) an OPO Transplant Coordinator is dispatched to the hospital. The Transplant Coordinator collaborates with the hospital care team to initiate an assessment of the patient for preliminary medical suitability for organ donation. The assessment includes chart review and physician-ordered blood tests to aid in identification of suitability and donation opportunities.[2]

Hospital staff support of patient

Hospital staff continues to support the patient and family and notifies the family of the patient's grave prognosis, including the cessation of brain function.

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[1] 42 C.F.R. § 482.45; 20 PA. CONS. STAT. § 8617(a).

[2] 42 C.F.R. § 486.344; 20 PA. CONS. STAT. § 8617(d).

2. Brain Death

Declaration of death

Physicians, medical ethicists, and state law are unanimous in their acceptance of brain death as death. It has been an accepted medical principle since the 1960s and has been a part of state law across the country since the early 1980s. Attached to this testimony as Appendix A is a recent article published in the New England Journal of Medicine addressing brain death and written by some of the most respected biomedical ethicists in the world.

The determination of brain death is addressed in Pennsylvania by state law unrelated to House Bill 30. Passed in 1981, Pennsylvania's Uniform Determination of Death Act is based on the Uniform Law Commission's model act. It provides that a person is brain dead where they have sustained an "irreversible cessation of all functions of the entire brain, including the brain stem" determined "in accordance with accepted medical standards."[3] Hospitals develop their internal brain death protocols in accordance with this statute and established medical criteria.

A brain death evaluation is initiated by hospital medical staff, not by an OPO. This typically requires two exams between 6 and 12 hours apart, performed by two separate physicians. **The physicians responsible for brain death testing are not involved in organ donation or recovery in any way.**[4] If the patient is pronounced brain dead, the family is notified by the hospital that death has occurred.

OPO contact with Coroner or Medical Examiner

Typically, after the first brain death exam is performed, the OPO contacts the Medical Examiner or Coroner ("ME/C") regarding the potential death and preliminary determination of a donation opportunity. The OPO contacts the ME/Coroner regarding every potential organ donor, regardless of the circumstances surrounding death in order ensure that the ME/C has full opportunity to be involved in every case.

Hospital and OPO collaborate on resources

The hospital care team and OPO collaborate to identify resources to be made available to the family including social work and pastoral care. The hospital and OPO collaborate on a plan to approach the family regarding donation in a manner sensitive to their circumstances. As part of the plan, the OPO checks advance health care directives and state driver's license registry for information regarding donor designation to share with the family.[5]

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[3] 35 P.S. § 10203.

[4] 20 PA. CONS. STAT. § 8616(b).

[5] 20 PA. CONS. STAT. § 8619(b).

3. The Donor Option

Family approach and initiation of donation discussion

As required by federal and state law, the OPO Transplant Coordinator, with the support of hospital staff, approach the family regarding the donation option in a manner encouraging discretion and sensitivity to the family's circumstances.[6] The coordinators are extensively trained before participating in these family interactions and most already have a background in critical care nursing. Their training is designed to ensure that the coordinator is an advocate for the donor and donor family, that they are experienced in understanding grief, and that they understand how to support families in the acute phases of loss. Overall, coordinators undergo 3 months of training comprised of didactic and clinical instruction under the guidance of clinical preceptors. They coordinate cases independently while being supervised by experienced coordinators and leadership staff for an additional 3 months before they are considered fully-trained. All coordinators at Gift of Life are expected to become Certified Procurement Transplant Coordinators after their first 12 months of service. Moreover, they must participate in 7 annual trainings, skills workshops, and continuing education programs.

If the decedent authorized donation before their death, information about the donation process is provided to the family. In the absence of a decision by the decedent regarding donation, authorization is requested from the next-of-kin according to statutory hierarchy.[7] While the family is notified of the donation option, the decedent's body is maintained on a ventilator.

The information reviewed with the family includes: (1) the organs and/or tissues that may be recovered; (2) the most likely uses for the donated organs or tissues; (3) a description of the screening and recovery processes; (4) information about the organizations that will recover, process, and distribute donated tissue; (5) information regarding access to and release of the donor's medical records; (6) an explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body; and (7) contact information for individual(s) with questions or concerns.[8]

Comprehensive medical/social history

If the decedent or their next-of-kin authorized donation, comprehensive medical and social history questionnaire similar to that used in blood donation is completed with the family or another appropriate historian. Diagnostic and other testing is performed to determine organ function, suitability for transplant, and to assist in allocation.

OPO and ME/C Collaboration

The OPO updates the ME/C regarding the declaration of death. The OPO then reviews with the ME/C the comprehensive report including known clinical information, organ function, injuries sustained, physical assessment, radiologic imaging, chest x-rays, CT scans, contact information

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[6] 42 C.F.R. § 486.342; 20 PA. CONS. STAT. § 8617(d).

[7] 42 C.F.R. § 486.342(a); 20 PA. CONS. STAT. § 8617(b).

[8] 42 C.F.R. § 486.342(a).

of any investigating agencies and other information in the hospital chart or collected from the family.

Until the ME/C makes a decision regarding jurisdiction, or if the ME/C assumes jurisdiction, the OPO inquires as to additional information relevant to their inquiry and requests permission to proceed with organ recovery. Certain ME/Cs (or their designee, such as a Deputy Coroner) travel on-site to the hospital at this point to initiate their review. The ME/C frequently request additional testing be performed at the hospital including toxicology, skeletal series and CT scans. Pictures, blood, bodily fluids, and tissue specimens are also frequently requested. Proper collection and documentation of these tests, specimens and pictures has proven to be sufficient for the ME/C to successfully conduct their investigations of potential homicides (including child abuse cases).

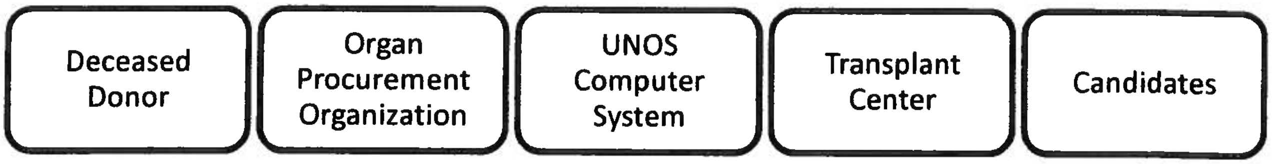
When permission to move forward with organ donation is granted, the ME/C and OPO coordinate timing of recovery, testing and imaging to be performed and samples to be collected.

Diagnostic and compatibility testing

Standard tests are performed to determine organ function, suitability for transplant, and to assist in allocation.

Organ donor and recipient matching

The OPO enters donor information and compatibility testing results into the national system and potential matches are identified. Organs are allocated based on those results.



4. Organ Recovery

Recovery procedure

The organ recovery procedure is scheduled to accommodate the interests of the donor family, ME/C, the donor hospital and transplant surgeons. Typically, the recovery takes place in the donor hospital operating room. If the ME/C has elected to participate in the recovery, they (or a designee) would be present for the procedure and could examine the organs in situ and post-recovery. If evidence relevant to the forensic investigation were identified with a particular organ, the ME/C would document the evidence and permit transplant to proceed, or withhold that organ as evidence. If the ME/C (or designee) does not attend the recovery, and during the recovery any additional findings are noted, the OPO communicates them to the ME/C prior to the recovery of the particular organ.

Surgical report

During the recovery procedure, information regarding the recovered organs is recorded by the transplanting surgeon and photographs of the organs are taken, all of which are made part of the donor record and shared with the ME/C.

OPO collaboration with ME/C post-recovery

Following the organ recovery procedure, the OPO notifies the ME/C that all requested testing, samples and other information is being transported together with the body to the location designated by the ME/C.

Additional information is available to the ME/C regarding the donation outcome and any post-transplant organ function to inform their forensic investigation. Transplant Surgeons will also be available to testify regarding the condition the organ and any other injuries noted while recovering the organ.

All of the above information is incorporated into the OPO donor record, which also includes certain checklists to ensure that all required information has been collected.

5. Family Support Services

Initial post-donation support

Supporting donor families after donation has long been an important part of the donation process for Gift of Life. The Family Support Services department (FSS) was created in 1990 and was one of the first of its kind among OPOs. Currently, the department has a several counselors dedicated to supporting the needs of organ and tissue donor families.

If a family chooses to authorize donation or if the deceased had the donor designation, we ask the family if they would like a donor recognition kit. If so, this package is sent within 72 hours so that the materials may be shared at the donor's funeral. The kit includes the following:

- A personalized certificate honoring the donor for their support of donation inserted in a custom made leatherette holder embossed with the Gift of Life Donor Medal
- *The Next Place* by Warren Hanson, which is a non-religious message about hope and compassion after the death of a loved one
- Donate Life/Done Vida green bracelets and a basket for display
- Donate Life lapel pins for the immediate family
- Additional Donate Life brochures and materials highlighting adding donor designation to a driver's license

Within 7 days of the donation, the Transplant Coordinator who spoke with the family sends a letter describing the gifts that were made and a general description of the transplant recipients (using de-identified information only). This letter also contains information about the services available through FSS.

Periodic follow-up

A few weeks after donation, an FSS counselor calls the legal next-of-kin to find out how they are coping and to see if they need Gift of Life to research community resources or counseling. After several attempts, if the family cannot be reached, FSS sends a letter to let them know we are hoping to contact them. Gift of Life also offers to family members eight free counseling sessions in our office in Philadelphia. The counselors in FSS follow up with the family members six months after the initial call, and hand-written notes are sent during the anniversary month.

FSS also coordinates annual Donor Family Remembrance Ceremonies. Gift of Life hosts five separate Donor Remembrance Ceremonies in Philadelphia, Harrisburg, the Scranton area, New Jersey and Delaware. Over 2,000 local organ and tissue donor families are invited to these ceremonies, which are designed to honor the donor and recognize the gifts they have given to help others. During the ceremony, every donor's name is called and their family members are invited to come to the front of the room and receive a donor medal, a flower, and a hand-knit wrap as a remembrance of their loved one.

Correspondence between donor families and recipients

Gift of Life coordinates the sharing of correspondence between donor families and the recipients of their loved ones' gifts. Information is provided to both groups about the letter-writing program and all are encouraged to begin the communication process through the OPO. Initially, only de-identified information is shared and confidentiality is maintained until the point that both donor family and recipient decide that they wish to share more personal or contact information.

Families often choose to meet after corresponding through the letter-writing program. If these circumstances present themselves, FSS will assist the families in facilitating this meeting. Often by the time recipients and donor families meet each other, they have developed a solid connection and the relationship continues to develop after the initial meeting.

II. Coordination with Law Enforcement

1. Best Practices

The outline above details best practices in coordinating organ donation with forensic investigations. In every single case, both donation and a complete forensic investigation can be conducted as has been proven true in several jurisdictions. **However, under House Bill 30 ME/Cs still retain absolute authority to prohibit organ recovery if they believe it will**

interfere with their forensic investigation.[9] The statutory obligation of an ME/C to determine cause, mechanism, and manner of death is, and under House Bill 30 remains, paramount.

Philadelphia County is an excellent example of the best practices in interactions between OPOs and law enforcement. Philadelphia has a Medical Examiner who is a board-certified forensic pathologist. Gift of Life maintains regular communication with the ME's office and notifies them of each death where donation is possible. Early in the process, the ME details the information, tests, samples and other materials they will need for their investigation. Gift of Life coordinates all donation activities to conform to the requests of the ME, and as a result donation is always permitted to proceed. In the event there were to be a forensic issue warranting the presence of a pathologist, the ME or their designee would join the recovery surgeons to ensure that all evidence is collected. Immediately after organ recovery, all evidence is transported with the decedent to the ME's facility for further investigation.

The process in Philadelphia County reinforces the fact that donation does not in any way interfere with a forensic investigation. For example, organ procurement does not preclude the performance of a "complete autopsy" or interfere with the collection of trace evidence at the hospitals.[10]

2. Variation in County Practice

House Bill 30 is essential because, unlike Philadelphia County, not all Coroners' offices have committed to ensuring donation opportunities are not lost. In the eastern half of Pennsylvania, only 4 counties represent 19 out of 24 total Coroner/ME denials in the past 10 years. In those counties healthy, transplantable organs are buried against the wishes of the deceased or next-of-kin.

The cases most frequently denied by Coroners are those where child abuse or SIDS is suspected. This is despite the fact that many jurisdictions (e.g. Philadelphia and New Jersey) routinely permit organ recovery in such cases. Moreover, Coroner declines of pediatric donors are especially tragic because pediatric donation is so rare. Children waiting for a transplant die at a rate 4 times greater than adults because in additional to all other criteria, a matching organ must be of an appropriate size.

New Jersey has had legislation similar to House Bill 30's Coroner/Medical Examiner provisions for 20 years.[11] In that time a Medical Examiner has never prohibited organ recovery and there has never been an instance where donation interfered with an investigation. According to the National Association of Medical Examiners, the same is true nationwide—organ donation does

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[9] House Bill 30, Session of 2013, Printer's No. 2125, at § 8627.

[10] J. Keith Pinckard, M.D., Ph.D., et al., Position Paper on the Medical Examiner Release of Organs and Tissues for Transplantation, National Association of Medical Examiners, Feb. 21, 2006, at 7.

[11] N.J. STAT. ANN. § 52:17B-88.8.

not interfere with forensic investigations.[12] It is unconscionable that a case where donation would be allowed to proceed in one county is rejected in another because of disparate practice. We believe that House Bill 30, by providing for attendance at recovery before denial, will limit or eliminate this variation in practice.

3. Effects of Coroner Declines

As mentioned, there have been 24 Coroner/ME declines in the eastern half of Pennsylvania over the past 10 years. Based on similar experience reported in the western half of Pennsylvania, it is likely that there have been approximately 50 total declines since 2004. On average, 2-3 organs are transplanted from each donor while as many as 8 transplants are possible. This means that approximately 100-150 (but possibly as many as 400) people in need of a transplant were denied that opportunity because of disparate practice across counties. During this same time period more than 5,000 people died awaiting transplant in Pennsylvania.[13]

III. Conclusion

Gift of Life Donor Program and the transplant community of Pennsylvania emphatically support House Bill 30. The reason is simple—House Bill 30 will increase organ donation and save lives. The organ donation process described above reflects the best opportunity for Pennsylvania to honor the wishes of every potential donor and donor family. These individuals, who in a time of tragedy nonetheless wish to help others through the miracle of organ donation, deserve nothing less than our best efforts to carry out their wishes. The 8,500 people waiting for a transplant in Pennsylvania deserve our best efforts to save their lives. The 429 people who died waiting in Pennsylvania last year deserve our best efforts to remedy the conditions that prevented them from receiving a life-saving transplant. For these reasons, we must pass House Bill 30.

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[12] Pinckard, et al., at 11.

[13] OPTN, Death Removals by Age by Year, (based on OPTN data as of May 2, 2014).

APPENDIX A

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Accepting Brain Death

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Two cases in which patients have been determined to be dead according to neurologic criteria ("brain death") have recently garnered national headlines. In Oakland, California, Jahi McMath's death was determined by means of multiple independent neurologic examinations, including one ordered by a court. Her family refused to accept that she had died and went to court to prevent physicians at Children's Hospital and Research Center in Oakland from discontinuing ventilator support. Per a court-supervised agreement, the body was given to the family 3 weeks after the initial determination. The family's attorney stated that ventilatory support was continued and nutritional support added at an undisclosed location.

In Fort Worth, Texas, Marlise Muñoz's body was maintained on mechanical ventilation for 8 weeks after the medical and legal criteria for death were met, in an attempt to "rescue" her fetus. Muñoz was 14 weeks pregnant when she died from pulmonary embolism. Her family asserted that continuing ventilatory support was contrary to what the patient would have wanted, but John Peter Smith Hospital cited a state law requiring that support not be terminated if a patient is pregnant. A judge ultimately ordered that the hospital follow the medically and legally indicated steps of declaring the patient dead and removing ventilatory support.
The McMath family's attorney claimed that their constitutional rights were violated and their religious beliefs (both about when death occurs and about prognosticating a possibility of recovery) were not respected. In making this argument, proponents of allowing family members to determine death threaten to undermine decades of law, medicine, and ethics.

The current U.S. approach to determining death was developed in response to the emergence of technologies that made the traditional standard of cardiopulmonary death problematic. In 1968, an ad hoc committee at Harvard Medical School published an influential article arguing for extending the concept of death to patients in an "irreversible coma."[1] The emerging neurologic criteria for death defined it in terms of loss of the functional activity of the brain stem and cerebral cortex. Although clinical criteria were developed in the 1960s, it took more than a decade for consensus over a rationale for the definition to emerge. In 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research provided a philosophical definition of brain death in terms of the loss of the critical functions of the organism as a whole.[2]

Shortly thereafter, the National Conference of Commissioners on Uniform State Laws produced the Uniform Determination of Death Act, which has been adopted in 45 states and recognized in the rest through judicial opinion.[3] In response to pressure from a vocal religious minority, New York and New Jersey added religious exceptions that affect the timing of the declaration of death. Even in these states, however, the vast majority of the time, the standard medical criteria for death are followed.

Over the past several decades, brain death has become well entrenched as a legal and medical definition of death. It is clearly defined by the neurologic community (see Determination of Brain Death), standards for diagnosis are in place, and it is established in law. It has become the primary basis of organ-procurement policy for transplantation. Ironically, the other standard for defining death, irreversible cessation of circulation, lacks consensus about diagnosis.

The concept of brain death has periodically come under criticism.[4] The primary objections focus on inadequacies in the philosophical rationale for the concept that the unifying functioning of the body has been lost with loss of brain functioning, combined with a concern that biologically, there is still a sense that the body is alive, often long after brain death occurs. Wound healing can continue to occur, most organs continue to function for some period, hormonal and body-temperature regulation may be maintained. It has been reported that a child's growth can continue. And as the Muñoz case demonstrates, a pregnancy can be maintained even after the pregnant woman has met the neurologic criteria for death.

Even many of the most vocal critics of brain death agree that there is no obligation to continue providing mechanical support after brain death. Although they do not consider brain death to be death, many of them agree that the person has ceased to exist and has no interests at stake in the discontinuation of ventilator support. Although some physicians accommodate a family's grief by allowing a brief delay either before completing brain-death examinations or before discontinuing mechanical support after a brain-death determination, these actions are for the family, not the patient. In addition, many believe that it is appropriate to procure organs after such declarations.

Unfortunately, these views raise severe difficulties for public policy. In a society tolerant of individual values and views, family views are appropriately given great weight in deciding exactly when to discontinue mechanical support. If brain death were not defined as death, it would be more difficult to justify routine decisions to discontinue mechanical support in this context. Families often need time to accept death, and that can be particularly complicated in cases of brain death. For the family's benefit, a short-term accommodation can be ethically justified. But these psychological realities do not undermine the important social construction of death when the brain has ceased all meaningful activity.

Rejecting brain death by shifting toward a more fluid and variable standard might undermine support for cadaveric organ donation. The "dead-donor rule," a fundamental concept of transplant ethics, requires that patients not be killed by the removal of vital organs necessary for life. Some critics of brain death seek to abandon the dead-donor rule. Whatever one thinks of the arguments for that as a philosophical position, it is far out of touch with currently accepted medical and legal standards and public opinion.5

We believe that there is no good reason to take such a drastic step. Dying is a process. Parts of the body die, and then other parts do. Eventually, gradually, all the cells die. Where in that process should the line between life and death be drawn? Given the brain's importance in determining who we are and its crucial role in driving the activity of bodily organs and systems, it is not surprising that loss of cortical and brain-stem function should be equated with death.

Seen in this light, the decision reached by the medical and particularly the neurology community to articulate and promulgate the concept of brain death as the right place to draw the line between life and death is extremely reasonable. There are clear medical criteria that can be reliably and reproducibly utilized to determine that death has occurred. If professional standards are followed properly, there are no false positives. Brain-dead patients are clearly past the point of any possibility of recovery. Although one could conceivably draw the line somewhere else, such as loss of cognitive functioning, the reliability and social consensus that has emerged around brain death as death is reflected in the broad legal agreement under which brain death is recognized in every state.

Medical and legal acceptance that the irreversible loss of brain functioning is death enables families to grieve the loss of their loved ones knowing that they were absolutely beyond recovery, as distinct from patients in a coma or a vegetative state. It errs on the side of certainty when organ procurement is requested. The determination of death is a highly significant social boundary. It determines who is recognized as a person with constitutional rights, who deserves legal entitlements and benefits, and when last wills and testaments become effective. Sound public policy requires bright lines backed up by agreed-on criteria, protocols, and tests when the issue is the determination of death. The law and ethics have long recognized that deferring to medical expertise regarding the diagnosis of brain death is the most reasonable way to manage the process of dying. Nothing in these two cases ought to change that stance.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

SOURCE INFORMATION

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Determination of Brain Death*

1. Absence of neurologic function with a known irreversible cause of coma
2. Correction of conditions affecting evaluation of brain death (performed before neurologic evaluation):
   - hypotension
   - hypothermia
   - metabolic disturbances
3. Discontinuation of medications affecting the neurologic examination (performed before neurologic evaluation):
   - sedatives
   - neuromuscular blockers
   - anticonvulsants
4. Timing of neurologic evaluation should be more than 24 to 48 hours after cardiopulmonary resuscitation or other severe acute brain injury
5. Duration of observation (pediatric cases):
   - 24 hours for neonates (37 weeks of gestation to 30 days after birth for term infants)
   - 12 hours for infants and children (>30 days to 18 years of age)
6. Clinical evaluation:
   - absence of pupillary response to a bright light
   - absence of movement of bulbar musculature
   - absence of gag, cough, sucking, and rooting reflexes shown by examining the cough response to tracheal suctioning
   - absence of corneal reflexes demonstrated by touching the cornea; no eyelid movement should be seen
   - absence of oculovestibular reflexes shown by irrigating each ear with ice water; movement of the eyes should be absent during 1 minute of observation
7. Apnea testing:
   - Pretest: confirmation of complete absence of spontaneous respiratory effort — preoxygenate with 100% oxygen, maintain core temperature above 35°C, normalize pH, blood pressure, and arterial blood gas (partial pressure of carbon dioxide [$\mathrm{Paco_2}$])
   - Test: demonstration of increase in arterial $\mathrm{Paco_2}$ of at least 20 mm Hg above baseline and of a total $\mathrm{Paco_2}$ of at least 60 mm Hg, with no observed respiration
   - Ancillary study: indication to perform if there is a medical contraindication to the apnea test, hemodynamic instability, desaturation to less than 85%, or the inability to reach a $\mathrm{Paco_2}$ of at least 60 mm Hg
   - Evidence of any respiratory effort is inconsistent with brain death, and the apnea test should be terminated
8. Ancillary studies:
   - electroencephalography
   - radionuclide cerebral blood flow
   - spinal cord reflexes if abnormal movements present

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* Derived from the American Academy of Neurology.

http://www.nejm.org/doi/full/10.1056/NEJMp1400930#t=article

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