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### **Organ Donation after Cardiac Death**

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Although the numbers of organ donors and transplantations in the United States have more than doubled over the past 20 years (see line graph), the demand for organs continues to dwarf

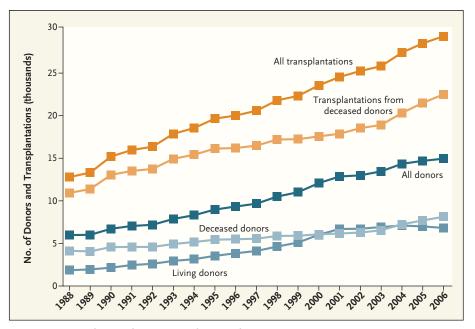
the supply. In 2006, there were about 29,000 solid-organ transplantations; as of June 2007, there were about 97,000 people on waiting lists for organ transplantation.

About three of every four organs that are transplanted are recovered from deceased donors. The most rapid increase in the rate of organ recovery from deceased persons has occurred in the category of donation after "cardiac death" — that is, a death declared on the basis of cardiopulmonary criteria (irreversible cessation of circulatory and respiratory function) rather than the neurologic criteria used to declare "brain death" (irrevers-

ible loss of all functions of the entire brain, including the brain stem). Organs were recovered from 645 donors after cardiac death in 2006, as compared with 189 in 2002; these donors accounted for 8% of all deceased donors in 2006 (see bar graph). At the Organ Procurement Organization at the University of Wisconsin, the New England Organ Bank in the Boston area, and the Finger Lakes Donor Recovery Network in New York, such donors accounted for more than 20% of all deceased donors.

Since 1968, when an ad hoc committee at Harvard Medical School proposed a brain-based definition of death that became widely accepted, organs for transplantation have been removed primarily from hospitalized patients who have been pronounced dead on the basis of neurologic criteria, when they are on ventilators and their hearts continue to function. The continued circulation of blood helps to prevent the organs from deteriorating.

Obtaining organs from donors after cardiac death — when the heart is no longer beating — is the approach that was generally followed in the 1960s and earlier. Today, such donations typically involve patients who are on a ventilator as the result of devastating and irreversible brain injuries, such as those caused by trauma or intracranial bleeding. Potential donors might also have high spinal cord injuries or end-stage musculoskeletal disease. Although such patients may be so near



Organ Donors and Transplantations in the United States, 1988–2006.

Data are from the Organ Procurement and Transplantation Network.

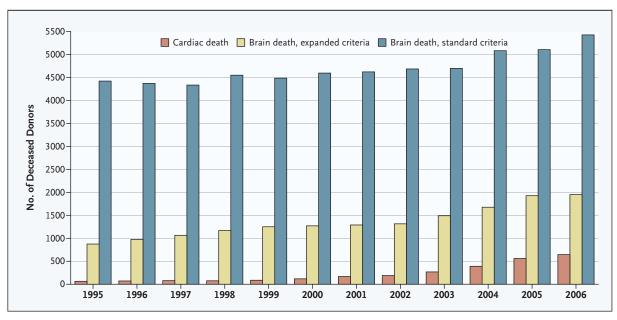
death that further treatment is futile, they are not dead.

The United Network for Organ Sharing, a private nonprofit group based in Richmond, Virginia, operates the Organ Procurement and Transplantation Network under contract with the federal government and is committed to increasing the number of donors. OPTN/UNOS, as the networks are collectively known, has developed rules for donation after cardiac death. According to these rules, finalized in March 2007, the process begins with the selection of a suitable candidate and the consent of the legal next of kin to the withdrawal of care and retrieval of organs (see box). Subsequently, life-sustaining measures are withdrawn under controlled circumstances in the intensive care unit (ICU) or the operating room; donation after an unexpected fatal cardiac arrest is rare.

When the potential donor meets the criteria for cardiac death, a doctor pronounces the patient dead. The time from the onset of asystole — the absence of sufficient cardiac activity to generate a pulse or blood flow (not necessarily the absence of all electrocardiographic activity) — to the declaration of death is generally about 5 minutes, but it may be as short as 2 minutes.1 The limited data available suggest that circulation does not spontaneously return after it has stopped for 2 minutes.2 The organs most commonly the kidneys and liver but also the pancreas, lungs, and, in rare cases, the heart are then recovered. To avoid obvious conflicts of interest, neither the surgeon who recovers the organs nor any other personnel involved in transplantation can participate in end-of-life care or the declaration of death.

The outcomes for organs transplanted after cardiac death are similar to those for organs transplanted after brain death. However, the length of time varies as to which organs can be deprived of oxygen (the interval from cessation of circulation to the initiation of perfusion with cold preservation solutions) and still be transplanted successfully. It is best to retrieve the liver less than 30 minutes after the withdrawal of life-sustaining measures; the kidneys and pancreas may often be recovered up to 60 minutes after such withdrawal.1 The extent of a patient's remaining circulatory and respiratory function may reveal whether death is likely to follow soon after extubation. If a patient does not die quickly enough to permit the recovery of organs, end-of-life care continues and any planned donation is canceled. At present, this may happen in up to 20% of cases.

In 1997, 2000, and 2005, the Institute of Medicine reviewed and voiced support for donation after cardiac death.3 In 2005, a conference on donation after cardiac death concluded that it is "an ethically acceptable practice of end-of-life care, capable of increasing the number of deceaseddonor organs available for transplantation."1 Nonetheless, some physicians and nurses at the bedside "continue to have concerns about the ethical propriety of the practice" that "are numerous, complex and related to the specific roles they play."4 Some feel uncomfortable about participation in medical practices that may be required during the transition from end-of-life care to organ donation.5 For example, in multidisciplinary ICUs, doctors and nurses who care for both potential organ donors and organ recipients may have conflicting interests. They may be uncomfortable



Distribution of Deceased Organ Donors in the United States, 1995-2006.

Organ donors who meet the standard criteria for donation after brain death are usually 59 years of age or younger. The expanded criteria for donation after brain death involve the use of organs from persons more than 60 years old and from persons 50 to 59 years old who have two or three of the following conditions: cerebrovascular accident as cause of death, a serum creatinine concentration of more than 1.5 mg per deciliter (133  $\mu$ mol per liter), and a history of hypertension. Data are from the Organ Procurement and Transplantation Network.

recommending the withdrawal of life-sustaining treatment for one patient and hoping to obtain an organ for another.

According to the "dead donor rule," donation should not cause or hasten death.3 As currently practiced, donation after cardiac death inevitably raises more concerns than donation after brain death. The process is more complex, and the potential donor is not dead when life-sustaining measures cease. The intervals between withdrawing care, pronouncing death, and recovering organs are very brief, and the family's relation to the dying process may be affected. In an interview, Sue McDiarmid, a professor of pediatrics and surgery at the University of California, Los Angeles, and the immediate past president of OPTN/UNOS, said, "The perception of some physicians and families is that the end-of-life experience is changed because organ procurement begins immediately after death has occurred. However, many families find great solace in the ability to donate organs under these special circumstances."

Concerns were raised by a February 2006 case in San Luis Obispo, California, that was publicized earlier this year by the Los Angeles Times. Two transplant surgeons were allegedly in the same room with a potential donor, and one of the surgeons allegedly ordered massive doses of morphine and lorazepam in an attempt to hasten the patient's death and thereby obtain his organs more quickly. The patient did not die for several hours, and his organs were not recovered because they were no longer usable for transplantation. The case,

which has been investigated by local law-enforcement authorities, is a sobering reminder that organdonation efforts can go terribly wrong if appropriate procedures are not followed.

Typically, potential donors are wheeled to the operating room when they are still alive. With explicit consent, heparin — possibly along with other agents is administered to maintain organ function. According to the 2005 Institute of Medicine conference, providing heparin at the time of withdrawal of life-sustaining treatment "is the current standard of care" because "the long-term survival of the transplanted organ may be at risk if thrombi impede circulation to the organ after reperfusion."1 Theoretically, heparin could hasten death by causing bleeding, but there is no evidence that it does

#### Elements of Protocols for Recovering Organs after Cardiac Death

All organ-procurement organizations and transplant centers in the United States must develop and comply with protocols to facilitate the recovery of organs from donors after cardiac death, according to the Organ Procurement and Transplantation Network and the United Network for Organ Sharing (known collectively as OPTN/UNOS). Listed here are "model elements" that the protocols are required to address, as adopted by the OPTN/UNOS board of directors in March 2007; they became effective on July 1, 2007.

#### **Donors**

- "A patient . . . who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for donation after cardiac death. Other conditions [may] include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury."
- "The decision to withdraw life-sustaining measures must be made by the hospital's patient care team and legal next of kin, and documented in the patient chart." Depending on the circumstances, the "legal next of kin" may be a relative, a designated health care representative, or an appropriate surrogate.
- The assessment of potential donors "should be conducted in collaboration with the local organ procurement organization and the patient's primary health care team." The medical director of the organ-procurement organization and transplant-center teams may be consulted.
- "An assessment should be made as to whether death is likely to occur (after the withdrawal of life-sustaining measures) within a time frame that allows for organ donation."

#### Consent and approval

- The legal next of kin may consent to the administration of drugs, such as heparin, or procedures, such as the placement of femoral catheters, for the purposes of organ donation. "No donor related medications shall be administered or donation related procedures performed without consent."
- Clearance from the medical examiner or coroner "must be obtained when applicable." There should be plans for continued endof-life care and immediate notification of the family "if death does not occur within the established timeframe after the withdrawal of life-sustaining measures."

#### Withdrawal of life-sustaining measures

- "A surgical timeout is recommended prior to the initiation of the withdrawal of life-sustaining measures." The intent is to verify patient identification and the roles and responsibilities of the various personnel.
- "No member of the transplant team shall be present for the withdrawal of life-sustaining measures," such as removal of an endotracheal tube or termination of medications for blood-pressure support. "No member of the organ recovery team or organ procurement organization staff may participate in the guidance or administration of palliative care, or the declaration of death."
- If applicable, placement of femoral catheters and the administration of heparin or other pharmacologic agents "for the sole purpose of donor organ function must be detailed in the consent process."

#### Pronouncement of death

"The patient care team member that is authorized to declare death must not be a member of the organ procurement organization or organ recovery transplant team. The method of declaring cardiac death must comply in all respects with the legal definition of death by an irreversible cessation of circulatory and respiratory function *before* the pronouncement of death."

#### Organ recovery

"Following the declaration of death by the hospital care team, the organ recovery may be initiated."

#### Financial considerations

"Organ procurement organization policy shall be to ensure that no donation related charges are passed to the donor family."

so in practice. Some protocols also call for the advance placement of catheters in large arteries and veins to facilitate the rapid infusion of organ-preservation solutions after death.<sup>1</sup>

In January 2007, the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) implemented its first accreditation standard for donation after cardiac death. According to this standard, hospitals with the necessary resources must develop donation policies in conjunction with their medical staff and their organ-procurement organization that ad-

dress "opportunities for asystolic recovery" of organs. Since many hospitals have never had an organ donor whose death was declared on the basis of cardiopulmonary criteria, meeting the standard may require new approaches to both organ donation and end-of-life care. The standard, however, re-

quires that relevant hospitals have the policies in place, not that they allow the practice — they can choose to opt out because of concerns about ethics, quality of endof-life care, or other reasons. When a hospital and its medical staff decide not to provide for donation after cardiac death and the organ-procurement organization is not in accord, the hospital must document its efforts to reach an agreement and include in the donation policy its justification for opting out. In addition, as of July 1, 2007, OPTN/UNOS has required all 257 transplant hospitals and 58 organ-procurement organizations in the United States to comply with its new rules.

If the number of organ donations after cardiac death continues to increase, more patients will be able to receive transplants. At present, however, these donations remain troubling to some and are not as widely accepted as donations after brain death.<sup>4,5</sup> Broader experience with the recommended practices should help, but concerns are likely to persist.

An interview with Francis Delmonico, chief of transplant services at Massachusetts General Hospital and medical director of the New England Organ Bank, and Michael Grodin, professor of health law, bioethics,

# and human rights at the Boston University School of Public Health can be heard at www.nejm.org.

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#### BECOMING A PHYSICIAN

## Leaving against Medical Advice

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It was the first day of my car-Ldiology subinternship, and I was trying to catch details of the 29-year-old patient's complex history. Juan Perez, a heroin addict who had undergone aortic-valve replacement years earlier, had been admitted overnight after presenting to the emergency department with acute onset of fever, chills, anorexia, and malaise; he was thought to have infectious endocarditis and severe aortic insufficiency. He was Puerto Rican and spoke only Spanish, despite having lived in Boston for many

Mr. Perez quickly became the focus of morning rounds. Through the open door, I glimpsed him half-lying on the hospital bed with one foot on the floor, wearing a sagging pair of Red Sox warm-up pants and no shirt. His

long, dark hair was pulled into a messy ponytail. He appeared well, considering the presentation I had just heard, except that his point of maximal impulse bulged visibly. The attending physician motioned for me to approach the bedside.

"Hola, señor," I offered. Mr. Perez met my eyes and smiled. "Hola, doctora."

"Vamos ahora a examinarlo, OK?" I laid my hand over his thin chest wall, smooth except for the scar from a median sternotomy. A displaced hyperdynamic impulse met my palm with each inefficient beat. The harsh systolic blow of severe mitral regurgitation came to life through my stethoscope, followed by a decrescendo wheeze of aortic insufficiency that overpowered the lung exam. Alarmed yet mesmerized, I listened to the

screech of an overloaded pump, picturing the dilated, thickened muscle squeezing furiously to maintain forward blood flow.

Mr. Perez's blood pressure, at 110/40, was classic for a patient with chronic aortic insufficiency. Our team searched for physical findings associated with widened pulse pressure, careful not to appear too eager. At the attending's urging, we gathered around Mr. Perez's left index finger to observe the capillary ebb and flow of Quincke's sign on his fingernail bed. Other eponymous gems I had read about but never seen were there for the taking: Traube's sign, the "pistol-shot" auscultated over the femoral artery, and Corrigan's "water-hammer" pulse in all its bounding glory. The more familiar Janeway lesions were evident on the plantar sur-